AMERICAN NATIONAL STANDARD

Quality management systems— Fundamentals and vocabulary

Approved as a American National Standard by:
American Society for Quality

An American National Standard Approved on December 13, 2000

Note: As used in this document, the term "International Standard" refers to the American National Standard adoption of this and other International Standards.

ASQ will consider requests for change and information on the submittal of such requests regarding this Standard. All requests should be in writing to the attention of the Standards administrator at the address below.

ASQ Mission: The American Society for Quality advances individual and organizational performance excellence worldwide by providing opportunities for learning, quality improvement, and knowledge exchange.

Published by:

American Society for Quality

ASQ

Quality Press
P.O. Box 3005
Milwaukee, Wisconsin 53201-3005
800-248-1946
Fax 414-272-1734
www.asq.org
http://qualitypress.asq.org
http://standardsgroup.asq.org

Contents

Page

Annex

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 9000 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 1, *Concepts and terminology*.

This second edition cancels and replaces ISO 8402:1994.

Annex A of this International Standard is for information only. It includes concept diagrams that provide a graphical representation of the relationships between terms in specific concept fields relative to quality management systems.

Introduction

0.1 General

The ISO 9000 family of standards listed below has been developed to assist organizations, of all types and sizes, to implement and operate effective quality management systems.

— ISO 9000 describes fundamentals of quality management systems and specifies the terminology for quality management systems.

— ISO 9001 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide products that fulfil customer and applicable regulatory requirements and aims to enhance customer satisfaction.

— ISO 9004 provides guidelines that consider both the effectiveness and efficiency of the quality management system. The aim of this standard is improvement of the performance of the organization and satisfaction of customers and other interested parties.

— ISO 19011 provides guidance on auditing quality and environmental management systems.

Together they form a coherent set of quality management system standards facilitating mutual understanding in national and international trade.

0.2 Quality management principles

To lead and operate an organization successfully, it is necessary to direct and control it in a systematic and transparent manner. Success can result from implementing and maintaining a management system that is designed to continually improve performance while addressing the needs of all interested parties. Managing an organization encompasses quality management amongst other management disciplines.

Eight quality management principles have been identified that can be used by top management in order to lead the organization towards improved performance.

a) **Customer focus**

Organizations depend on their customers and therefore should understand current and future customer needs, should meet customer requirements and strive to exceed customer expectations.

b) **Leadership**

Leaders establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization's objectives.

c) **Involvement of people**

People at all levels are the essence of an organization and their full involvement enables their abilities to be used for the organization's benefit.

d) **Process approach**

A desired result is achieved more efficiently when activities and related resources are managed as a process.

e) **System approach to management**

Identifying, understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its objectives.

f) **Continual improvement**

Continual improvement of the organization's overall performance should be a permanent objective of the organization.

g) **Factual approach to decision making**

Effective decisions are based on the analysis of data and information.

h) **Mutually beneficial supplier relationships**

An organization and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value.

These eight quality management principles form the basis for the quality management system standards within the ISO 9000 family.

Quality management systems — Fundamentals and vocabulary

1 Scope

This International Standard describes fundamentals of quality management systems, which form the subject of the ISO 9000 family, and defines related terms.

This International Standard is applicable to the following:

a) organizations seeking advantage through the implementation of a quality management system;

b) organizations seeking confidence from their suppliers that their product requirements will be satisfied;

c) users of the products;

d) those concerned with a mutual understanding of the terminology used in quality management (e.g. suppliers, customers, regulators);

e) those internal or external to the organization who assess the quality management system or audit it for conformity with the requirements of ISO 9001 (e.g. auditors, regulators, certification/registration bodies);

f) those internal or external to the organization who give advice or training on the quality management system appropriate to that organization;

g) developers of related standards.

2 Fundamentals of quality management systems

2.1 Rationale for quality management systems

Quality management systems can assist organizations in enhancing customer satisfaction.

Customers require products with characteristics that satisfy their needs and expectations. These needs and expectations are expressed in product specifications and collectively referred to as customer requirements. Customer requirements may be specified contractually by the customer or may be determined by the organization itself. In either case, the customer ultimately determines the acceptability of the product. Because customer needs and expectations are changing, and because of competitive pressures and technical advances, organizations are driven to improve continually their products and processes.

The quality management system approach encourages organizations to analyse customer requirements, define the processes that contribute to the achievement of a product which is acceptable to the customer, and keep these processes under control. A quality management system can provide the framework for continual improvement to increase the probability of enhancing customer satisfaction and the satisfaction of other interested parties. It provides confidence to the organization and its customers that it is able to provide products that consistently fulfil requirements.

2.2 Requirements for quality management systems and requirements for products

The ISO 9000 family distinguishes between requirements for quality management systems and requirements for products.

Requirements for quality management systems are specified in ISO 9001. Requirements for quality management systems are generic and applicable to organizations in any industry or economic sector regardless of the offered product category. ISO 9001 itself does not establish requirements for products.

Requirements for products can be specified by customers or by the organization in anticipation of customer requirements, or by regulation. The requirements for products and in some cases associated processes can be contained in, for example, technical specifications, product standards, process standards, contractual agreements and regulatory requirements.

2.3 Quality management systems approach

An approach to developing and implementing a quality management system consists of several steps including the following:

a) determining the needs and expectations of customers and other interested parties;

b) establishing the quality policy and quality objectives of the organization;

c) determining the processes and responsibilities necessary to attain the quality objectives;

d) determining and providing the resources necessary to attain the quality objectives;

e) establishing methods to measure the effectiveness and efficiency of each process;

f) applying these measures to determine the effectiveness and efficiency of each process;

g) determining means of preventing nonconformities and eliminating their causes;

h) establishing and applying a process for continual improvement of the quality management system.

Such an approach is also applicable to maintaining and improving an existing quality management system.

An organization that adopts the above approach creates confidence in the capability of its processes and the quality of its products, and provides a basis for continual improvement. This can lead to increased satisfaction of customers and other interested parties and to the success of the organization.

2.4 The process approach

Any activity, or set of activities, that uses resources to transform inputs to outputs can be considered as a process.

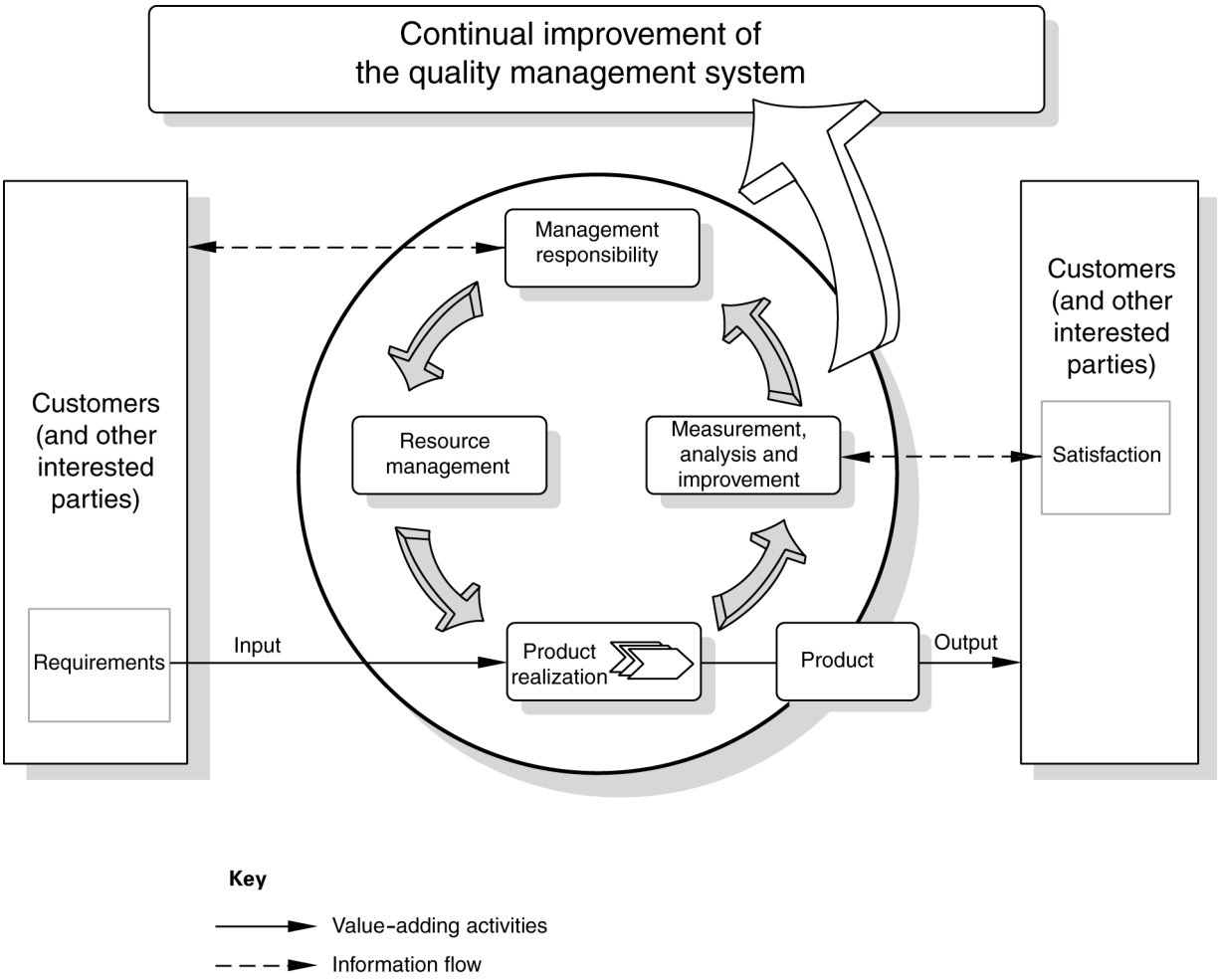
For organizations to function effectively, they have to identify and manage numerous interrelated and interacting processes. Often, the output from one process will directly form the input into the next process. The systematic identification and management of the processes employed within an organization and particularly the interactions between such processes is referred to as the “process approach”.

The intent of this International Standard is to encourage the adoption of the process approach to manage an organization.

Figure 1 illustrates the process-based quality management system described the ISO 9000 family of standards. This illustration shows that interested parties play a significant role in providing inputs to the organization. Monitoring the satisfaction of interested parties requires the evaluation of information relating to the perception of interested parties as to the extent to which their needs and expectations have been met. The model shown in Figure 1 does not show processes at a detailed level.

2.5 Quality policy and quality objectives

Quality policy and quality objectives are established to provide a focus to direct the organization. Both determine the desired results and assist the organization to apply its resources to achieve these results. The quality policy provides a framework for establishing and reviewing quality objectives. The quality objectives need to be consistent with the quality policy and the commitment to continual improvement, and their achievement needs to be measurable. The achievement of quality objectives can have a positive impact on product quality, operational effectiveness and financial performance and thus on the satisfaction and confidence of interested parties.



NOTE Statements in parentheses do not apply to ISO 9001.

Figure 1 — Model of a process-based quality management system

2.6 Role of top management within the quality management system

Through leadership and actions, top management can create an environment where people are fully involved and in which a quality management system can operate effectively. The quality management principles (see 0.2) can be used by top management as the basis of its role, which is as follows:

a) to establish and maintain the quality policy and quality objectives of the organization;

b) to promote the quality policy and quality objectives throughout the organization to increase awareness, motivation and involvement;

c) to ensure focus on customer requirements throughout the organization;

d) to ensure that appropriate processes are implemented to enable requirements of customers and other interested parties to be fulfilled and quality objectives to be achieved;

e) to ensure that an effective and efficient quality management system is established, implemented and maintained to achieve these quality objectives;

f) to ensure the availability of necessary resources;

g) to review the quality management system periodically;

h) to decide on actions regarding the quality policy and quality objectives;

i) to decide on actions for improvement of the quality management system.

2.7 Documentation

2.7.1 Value of documentation

Documentation enables communication of intent and consistency of action. Its use contributes to

a) achievement of conformity to customer requirements and quality improvement,

b) provision of appropriate training,

c) repeatability and traceability,

d) provision of objective evidence, and

e) evaluation of the effectiveness and continuing suitability of the quality management system.

Generation of documentation should not be an end in itself but should be a value-adding activity.

2.7.2 Types of document used in quality management systems

The following types of document are used in quality management systems:

a) documents that provide consistent information, both internally and externally, about the organization's quality management system; such documents are referred to as quality manuals;

b) documents that describe how the quality management system is applied to a specific product, project or contract; such documents are referred to as quality plans;

c) documents stating requirements; such documents are referred to as specifications;

d) documents stating recommendations or suggestions; such documents are referred to as guidelines;

e) documents that provide information about how to perform activities and processes consistently; such documents can include documented procedures, work instructions and drawings;

f) documents that provide objective evidence of activities performed or results achieved; such documents are referred to as records.

Each organization determines the extent of documentation required and the media to be used. This depends on factors such as the type and size of the organization, the complexity and interaction of processes, the complexity of products, customer requirements, the applicable regulatory requirements, the demonstrated ability of personnel, and the extent to which it is necessary to demonstrate fulfilment of quality management system requirements.

2.8 Evaluating quality management systems

2.8.1 Evaluating processes within the quality management system

When evaluating quality management systems, there are four basic questions that should be asked in relation to every process being evaluated.

a) Is the process identified and appropriately defined?

b) Are responsibilities assigned?

c) Are the procedures implemented and maintained?

d) Is the process effective in achieving the required results?

The collective answers to the above questions can determine the result of the evaluation. Evaluation of a quality management system can vary in scope and encompass a range of activities, such as auditing and reviewing the quality management system, and self-assessments.

2.8.2 Auditing the quality management system

Audits are used to determine the extent to which the quality management system requirements are fulfilled. Audit findings are used to assess the effectiveness of the quality management system and to identify opportunities for improvement.

First-party audits are conducted by, or on behalf of, the organization itself for internal purposes and can form the basis for an organization's self-declaration of conformity.

Second-party audits are conducted by customers of the organization or by other persons on behalf of the customer.

Third-party audits are conducted by external independent organizations. Such organizations, usually accredited, provide certification or registration of conformity with requirements such as those of ISO 9001.

ISO 19011 provides guidance on auditing.

2.8.3 Reviewing the quality management system

One role of top management is to carry out regular systematic evaluations of the suitability, adequacy, effectiveness and efficiency of the quality management system with respect to the quality policy and quality objectives. This review can include consideration of the need to adapt the quality policy and objectives in response to changing needs and expectations of interested parties. The review includes determination of the need for actions.

Amongst other sources of information, audit reports are used for review of the quality management system.

2.8.4 Self-assessment

An organization's self-assessment is a comprehensive and systematic review of the organization's activities and results referenced against the quality management system or a model of excellence.

Self-assessment can provide an overall view of the performance of the organization and the degree of maturity of the quality management system. It can also help to identify areas requiring improvement in the organization and to determine priorities.

2.9 Continual improvement

The aim of continual improvement of a quality management system is to increase the probability of enhancing the satisfaction of customers and other interested parties. Actions for improvement include the following:

a) analysing and evaluating the existing situation to identify areas for improvement;

b) establishing the objectives for improvement;

c) searching for possible solutions to achieve the objectives;

d) evaluating these solutions and making a selection;

e) implementing the selected solution;

f) measuring, verifying, analysing and evaluating results of the implementation to determine that the objectives have been met;

g) formalizing changes.

Results are reviewed, as necessary, to determine further opportunities for improvement. In this way, improvement is a continual activity. Feedback from customers and other interested parties, audits and review of the quality management system can also be used to identify opportunities for improvement.

2.10 Role of statistical techniques

The use of statistical techniques can help in understanding variability, and thereby can help organizations to solve problems and improve effectiveness and efficiency. These techniques also facilitate better use of available data to assist in decision making.

Variability can be observed in the behaviour and outcome of many activities, even under conditions of apparent stability. Such variability can be observed in measurable characteristics of products and processes, and may be seen to exist at various stages over the life cycle of products from market research to customer service and final disposal.

Statistical techniques can help to measure, describe, analyse, interpret and model such variability, even with a relatively limited amount of data. Statistical analysis of such data can help to provide a better understanding of the nature, extent and causes of variability, thus helping to solve and even prevent problems that may result from such variability, and to promote continual improvement.

Guidance on statistical techniques in a quality management system is given in ISO/TR 10017.

2.11 Quality management systems and other management system focuses

The quality management system is that part of the organization's management system that focuses on the achievement of results, in relation to the quality objectives, to satisfy the needs, expectations and requirements of interested parties, as appropriate. The quality objectives complement other objectives of the organization such as those related to growth, funding, profitability, the environment and occupational health and safety. The various parts of an organization's management system might be integrated, together with the quality management system, into a single management system using common elements. This can facilitate planning, allocation of resources, definition of complementary objectives and evaluation of the overall effectiveness of the organization. The organization's management system can be assessed against the organization's management system requirements. The management system can also be audited against the requirements of International Standards such as ISO 9001 and ISO 14001:1996. These management system audits can be carried out separately or in combination.

2.12 Relationship between quality management systems and excellence models

The approaches of quality management systems given in the ISO 9000 family of standards and in organizational excellence models are based on common principles. Both approaches

a) enable an organization to identify its strengths and weaknesses,

b) contain provision for evaluation against generic models,

c) provide a basis for continual improvement, and

d) contain provision for external recognition.

The difference between the approaches of the quality management systems in the ISO 9000 family and the excellence models lies in their scope of application. The ISO 9000 family of standards provides requirements for quality management systems and guidance for performance improvement; evaluation of quality management systems determines fulfilment of those requirements. The excellence models contain criteria that enable comparative evaluation of organizational performance and this is applicable to all activities and all interested parties of an organization. Assessment criteria in excellence models provide a basis for an organization to compare its performance with the performance of other organizations.

3 Terms and definitions

A term in a definition or note which is defined elsewhere in this clause is indicated by boldface followed by its entry number in parentheses. Such a boldface term may be replaced in the definition by its complete definition. For example:

product (3.4.2) is defined as “result of a **process** (3.4.1)”;

process is defined as “set of interrelated or interacting activities which transforms inputs into outputs”.

If the term “**process**” is replaced by its definition, as follows:

product then becomes “result of a set of interrelated or interacting activities which transforms inputs into outputs”.

A concept limited to a special meaning in a particular context is indicated by designating the subject field in angle brackets, 〈 〉, before the definition, for example, **technical expert** 〈audit〉 (3.9.11).

3.1 Terms relating to quality

3.1.1
quality
degree to which a set of inherent **characteristics** (3.5.1) fulfils **requirements** (3.1.2)

NOTE 1 The term “quality” can be used with adjectives such as poor, good or excellent.

NOTE 2 “Inherent”, as opposed to “assigned”, means existing in something, especially as a permanent characteristic.

3.1.2
requirement
need or expectation that is stated, generally implied or obligatory

NOTE 1 “Generally implied” means that it is custom or common practice for the **organization** (3.3.1), its **customers** (3.3.5) and other **interested parties** (3.3.7), that the need or expectation under consideration is implied.

NOTE 2 A qualifier can be used to denote a specific type of requirement, e.g. product requirement, quality management requirement, customer requirement.

NOTE 3 A specified requirement is one which is stated, for example, in a **document** (3.7.2).

NOTE 4 Requirements can be generated by different interested parties.

3.1.3
grade
category or rank given to different quality **requirements** (3.1.2) for **products** (3.4.2), **processes** (3.4.1) or **systems** (3.2.1) having the same functional use

EXAMPLE Class of airline ticket and category of hotel in a hotel guide.

NOTE When establishing a quality requirement, the grade is generally specified.

3.1.4
customer satisfaction
customer's perception of the degree to which the customer's **requirements** (3.1.2) have been fulfilled

NOTE 1 Customer complaints are a common indicator of low customer satisfaction but their absence does not necessarily imply high customer satisfaction.

NOTE 2 Even when customer requirements have been agreed with the customer and fulfilled, this does not necessarily ensure high customer satisfaction.

3.1.5
capability
ability of an **organization** (3.3.1), **system** (3.2.1) or **process** (3.4.1) to realize a **product** (3.4.2) that will fulfil the **requirements** (3.1.2) for that product

NOTE Process capability terms in the field of statistics are defined in ISO 3534-2.

3.2 Terms relating to management

3.2.1
system
set of interrelated or interacting elements

3.2.2
management system
system (3.2.1) to establish policy and objectives and to achieve those objectives

NOTE A management system of an **organization** (3.3.1) can include different management systems, such as a **quality management system** (3.2.3), a financial management system or an environmental management system.

3.2.3
quality management system
management system (3.2.2) to direct and control an **organization** (3.3.1) with regard to **quality** (3.1.1)

3.2.4
quality policy
overall intentions and direction of an **organization** (3.3.1) related to **quality** (3.1.1) as formally expressed by **top management** (3.2.7)

NOTE 1 Generally the quality policy is consistent with the overall policy of the organization and provides a framework for the setting of **quality objectives** (3.2.5).

NOTE 2 Quality management principles presented in this International Standard can form a basis for the establishment of a quality policy. (See 0.2.)

3.2.5
quality objective
something sought, or aimed for, related to **quality** (3.1.1)

NOTE 1 Quality objectives are generally based on the organization's **quality policy** (3.2.4).

NOTE 2 Quality objectives are generally specified for relevant functions and levels in the **organization** (3.3.1).

3.2.6
management
coordinated activities to direct and control an **organization** (3.3.1)

NOTE In English, the term “management” sometimes refers to people, i.e. a person or group of people with authority and responsibility for the conduct and control of an organization. When “management” is used in this sense it should always be used with some form of qualifier to avoid confusion with the concept “management” defined above. For example, “management shall…” is deprecated whereas “**top management** (3.2.7) shall…” is acceptable.

3.2.7
top management
person or group of people who directs and controls an **organization** (3.3.1) at the highest level

3.2.8
quality management
coordinated activities to direct and control an **organization** (3.3.1) with regard to **quality** (3.1.1)

NOTE Direction and control with regard to quality generally includes establishment of the **quality policy** (3.2.4) and **quality objectives** (3.2.5), **quality planning** (3.2.9), **quality control** (3.2.10), **quality assurance** (3.2.11) and **quality improvement** (3.2.12).

3.2.9
quality planning
part of **quality management** (3.2.8) focused on setting **quality objectives** (3.2.5) and specifying necessary operational **processes** (3.4.1) and related resources to fulfil the quality objectives

NOTE Establishing **quality plans** (3.7.5) can be part of quality planning.

3.2.10
quality control
part of **quality management** (3.2.8) focused on fulfilling quality **requirements** (3.1.2)

3.2.11
quality assurance
part of **quality management** (3.2.8) focused on providing confidence that quality **requirements** (3.1.2) will be fulfilled

3.2.12
quality improvement
part of **quality management** (3.2.8) focused on increasing the ability to fulfil quality **requirements** (3.1.2)

NOTE The requirements can be related to any aspect such as **effectiveness** (3.2.14), **efficiency** (3.2.15) or **traceability** (3.5.4).

3.2.13
continual improvement
recurring activity to increase the ability to fulfil **requirements** (3.1.2)

NOTE The **process** (3.4.1) of establishing objectives and finding opportunities for improvement is a continual process through the use of **audit findings** (3.9.5) and **audit conclusions** (3.9.6), analysis of data, management **reviews** (3.8.7) or other means and generally leads to **corrective action** (3.6.5) or **preventive action** (3.6.4).

3.2.14
effectiveness
extent to which planned activities are realized and planned results achieved

3.2.15
efficiency
relationship between the result achieved and the resources used

3.3 Terms relating to organization

3.3.1
organization
group of people and facilities with an arrangement of responsibilities, authorities and relationships

EXAMPLE Company, corporation, firm, enterprise, institution, charity, sole trader, association, or parts or combination thereof.

NOTE 1 The arrangement is generally orderly.

NOTE 2 An organization can be public or private.

NOTE 3 This definition is valid for the purposes of **quality management system** (3.2.3) standards. The term “organization” is defined differently in ISO/IEC Guide 2.

3.3.2
organizational structure
arrangement of responsibilities, authorities and relationships between people

NOTE 1 The arrangement is generally orderly.

NOTE 2 A formal expression of the organizational structure is often provided in a **quality manual** (3.7.4) or a **quality plan** (3.7.5) for a **project** (3.4.3).

NOTE 3 The scope of an organizational structure can include relevant interfaces to external **organizations** (3.3.1).

3.3.3
infrastructure
〈organization〉 system of facilities, equipment and services needed for the operation of an **organization** (3.3.1)

3.3.4
work environment
set of conditions under which work is performed

NOTE Conditions include physical, social, psychological and environmental factors (such as temperature, recognition schemes, ergonomics and atmospheric composition).

3.3.5
customer
organization (3.3.1) or person that receives a **product** (3.4.2)

EXAMPLE Consumer, client, end-user, retailer, beneficiary and purchaser.

NOTE A customer can be internal or external to the organization.

3.3.6
supplier
organization (3.3.1) or person that provides a **product** (3.4.2)

EXAMPLE Producer, distributor, retailer or vendor of a product, or provider of a service or information.

NOTE 1 A supplier can be internal or external to the organization.

NOTE 2 In a contractual situation a supplier is sometimes called “contractor”.

3.3.7
interested party
person or group having an interest in the performance or success of an **organization** (3.3.1)

EXAMPLE **Customers** (3.3.5), owners, people in an organization, **suppliers** (3.3.6), bankers, unions, partners or society.

NOTE A group can comprise an organization, a part thereof, or more than one organization.

3.4 Terms relating to process and product

3.4.1
process
set of interrelated or interacting activities which transforms inputs into outputs

NOTE 1 Inputs to a process are generally outputs of other processes.

NOTE 2 Processes in an **organization** (3.3.1) are generally planned and carried out under controlled conditions to add value.

NOTE 3 A process where the **conformity** (3.6.1) of the resulting **product** (3.4.2) cannot be readily or economically verified is frequently referred to as a “special process”.

3.4.2
product
result of a **process** (3.4.1)

NOTE 1 There are four generic product categories, as follows:

— services (e.g. transport);

— software (e.g. computer program, dictionary);

— hardware (e.g. engine mechanical part);

— processed materials (e.g. lubricant).

Many products comprise elements belonging to different generic product categories. Whether the product is then called service, software, hardware or processed material depends on the dominant element. For example the offered product “automobile” consists of hardware (e.g. tyres), processed materials (e.g. fuel, cooling liquid), software (e.g. engine control software, driver's manual), and service (e.g. operating explanations given by the salesman).

NOTE 2 Service is the result of at least one activity necessarily performed at the interface between the **supplier** (3.3.6) and **customer** (3.3.5) and is generally intangible. Provision of a service can involve, for example, the following:

— an activity performed on a customer-supplied tangible product (e.g. automobile to be repaired);

— an activity performed on a customer-supplied intangible product (e.g. the income statement needed to prepare a tax return);

— the delivery of an intangible product (e.g. the delivery of information in the context of knowledge transmission);

— the creation of ambience for the customer (e.g. in hotels and restaurants).

Software consists of information and is generally intangible and can be in the form of approaches, transactions or **procedures** (3.4.5).

Hardware is generally tangible and its amount is a countable **characteristic** (3.5.1). Processed materials are generally tangible and their amount is a continuous characteristic. Hardware and processed materials often are referred to as goods.

NOTE 3 **Quality assurance** (3.2.11) is mainly focused on intended product.

3.4.3
project
unique **process** (3.4.1), consisting of a set of coordinated and controlled activities with start and finish dates, undertaken to achieve an objective conforming to specific **requirements** (3.1.2), including the constraints of time, cost and resources

NOTE 1 An individual project can form part of a larger project structure.

NOTE 2 In some projects the objectives are refined and the product **characteristics** (3.5.1) defined progressively as the project proceeds.

NOTE 3 The outcome of a project may be one or several units of **product** (3.4.2).

NOTE 4 Adapted from ISO 10006:1997.

3.4.4
design and development
set of **processes** (3.4.1) that transforms **requirements** (3.1.2) into specified **characteristics** (3.5.1) or into the **specification** (3.7.3) of a **product** (3.4.2), **process** (3.4.1) or **system** (3.2.1)

NOTE 1 The terms “design” and “development” are sometimes used synonymously and sometimes used to define different stages of the overall design and development process.

NOTE 2 A qualifier can be applied to indicate the nature of what is being designed and developed (e.g. product design and development or process design and development).

3.4.5
procedure
specified way to carry out an activity or a **process** (3.4.1)

NOTE 1 Procedures can be documented or not.

NOTE 2 When a procedure is documented, the term “written procedure” or “documented procedure” is frequently used. The **document** (3.7.2) that contains a procedure can be called a “procedure document”.

3.5 Terms relating to characteristics

3.5.1
characteristic
distinguishing feature

NOTE 1 A characteristic can be inherent or assigned.

NOTE 2 A characteristic can be qualitative or quantitative.

NOTE 3 There are various classes of characteristic, such as the following:

— physical (e.g. mechanical, electrical, chemical or biological characteristics);

— sensory (e.g. related to smell, touch, taste, sight, hearing);

— behavioral (e.g. courtesy, honesty, veracity);

— temporal (e.g. punctuality, reliability, availability);

— ergonomic (e.g. physiological characteristic, or related to human safety);

— functional (e.g. maximum speed of an aircraft).

3.5.2
quality characteristic
inherent **characteristic** (3.5.1) of a **product** (3.4.2), **process** (3.4.1) or **system** (3.2.1) related to a **requirement** (3.1.2)

NOTE 1 Inherent means existing in something, especially as a permanent characteristic.

NOTE 2 A characteristic assigned to a product, process or system (e.g. the price of a product, the owner of a product) is not a quality characteristic of that product, process or system.

3.5.3
dependability
collective term used to describe the availability performance and its influencing factors: reliability performance, maintainability performance and maintenance support performance

NOTE Dependability is used only for general descriptions in non-quantitative terms.

[IEC 60050-191:1990].

3.5.4
traceability
ability to trace the history, application or location of that which is under consideration

NOTE 1 When considering **product** (3.4.2), traceability can relate to

— the origin of materials and parts,

— the processing history, and

— the distribution and location of the product after delivery.

NOTE 2 In the field of metrology the definition in VIM:1993, 6.10, is the accepted definition.

3.6 Terms relating to conformity

3.6.1
conformity
fulfilment of a **requirement** (3.1.2)

NOTE 1 This definition is consistent with ISO/IEC Guide 2 but differs from it in phrasing to fit into the ISO 9000 concepts.

NOTE 2 The term “conformance” is synonymous but deprecated.

3.6.2
nonconformity
non-fulfilment of a **requirement** (3.1.2)

3.6.3
defect
non-fulfilment of a **requirement** (3.1.2) related to an intended or specified use

NOTE 1 The distinction between the concepts defect and **nonconformity** (3.6.2) is important as it has legal connotations, particularly those associated with product liability issues. Consequently the term “defect” should be used with extreme caution.

NOTE 2 The intended use as intended by the **customer** (3.3.5) can be affected by the nature of the information, such as operating or maintenance instructions, provided by the **supplier** (3.3.6).

3.6.4
preventive action
action to eliminate the cause of a potential **nonconformity** (3.6.2) or other undesirable potential situation

NOTE 1 There can be more than one cause for a potential nonconformity.

NOTE 2 Preventive action is taken to prevent occurrence whereas **corrective action** (3.6.5) is taken to prevent recurrence.

3.6.5
corrective action
action to eliminate the cause of a detected **nonconformity** (3.6.2) or other undesirable situation

NOTE 1 There can be more than one cause for a nonconformity.

NOTE 2 Corrective action is taken to prevent recurrence whereas **preventive action** (3.6.4) is taken to prevent occurrence.

NOTE 3 There is a distinction between **correction** (3.6.6) and corrective action.

3.6.6
correction
action to eliminate a detected **nonconformity** (3.6.2)

NOTE 1 A correction can be made in conjunction with a **corrective action** (3.6.5).

NOTE 2 A correction can be, for example, **rework** (3.6.7) or **regrade** (3.6.8).

3.6.7
rework
action on a nonconforming **product** (3.4.2) to make it conform to the **requirements** (3.1.2)

NOTE Unlike rework, **repair** (3.6.9) can affect or change parts of the nonconforming product.

3.6.8
regrade
alteration of the **grade** (3.1.3) of a nonconforming **product** (3.4.2) in order to make it conform to **requirements** (3.1.2) differing from the initial ones

3.6.9
repair
action on a nonconforming **product** (3.4.2) to make it acceptable for the intended use

NOTE 1 Repair includes remedial action taken on a previously conforming product to restore it for use, for example as part of maintenance.

NOTE 2 Unlike **rework** (3.6.7), repair can affect or change parts of the nonconforming product.

3.6.10
scrap
action on a nonconforming **product** (3.4.2) to preclude its originally intended use

EXAMPLE Recycling, destruction.

NOTE In a nonconforming service situation, use is precluded by discontinuing the service.

3.6.11
concession
permission to use or release a **product** (3.4.2) that does not conform to specified **requirements** (3.1.2)

NOTE A concession is generally limited to the delivery of a product that has nonconforming **characteristics** (3.5.1) within specified limits for an agreed time or quantity of that product.

3.6.12
deviation permit
permission to depart from the originally specified **requirements** (3.1.2) of a **product** (3.4.2) prior to realization

NOTE A deviation permit is generally given for a limited quantity of product or period of time, and for a specific use.

3.6.13
release
permission to proceed to the next stage of a **process** (3.4.1)

NOTE In English, in the context of computer software, the term “release” is frequently used to refer to a version of the software itself.

3.7 Terms relating to documentation

3.7.1
information
meaningful data

3.7.2
document
information (3.7.1) and its supporting medium

EXAMPLE **Record** (3.7.6), **specification** (3.7.3), procedure document, drawing, report, standard.

NOTE 1 The medium can be paper, magnetic, electronic or optical computer disc, photograph or master sample, or a combination thereof.

NOTE 2 A set of documents, for example specifications and records, is frequently called “documentation”.

NOTE 3 Some **requirements** (3.1.2) (e.g. the requirement to be readable) relate to all types of documents, however there can be different requirements for specifications (e.g. the requirement to be revision controlled) and records (e.g. the requirement to be retrievable).

3.7.3
specification
document (3.7.2) stating **requirement**s (3.1.2)

NOTE A specification can be related to activities (e.g. procedure document, process specification and test specification), or **products** (3.4.2) (e.g. product specification, performance specification and drawing).

3.7.4
quality manual
document (3.7.2) specifying the **quality management system** (3.2.3) of an **organization** (3.3.1)

NOTE Quality manuals can vary in detail and format to suit the size and complexity of an individual organization.

3.7.5
quality plan
document (3.7.2) specifying which **procedures** (3.4.5) and associated resources shall be applied by whom and when to a specific **project** (3.4.3), **product** (3.4.2), **process** (3.4.1) or contract

NOTE 1 These procedures generally include those referring to quality management processes and to product realization processes.

NOTE 2 A quality plan often makes reference to parts of the **quality manual** (3.7.4) or to procedure documents.

NOTE 3 A quality plan is generally one of the results of **quality planning** (3.2.9).

3.7.6
record
document (3.7.2) stating results achieved or providing evidence of activities performed

NOTE 1 Records can be used, for example, to document **traceability** (3.5.4) and to provide evidence of **verification** (3.8.4), **preventive action** (3.6.4) and **corrective action** (3.6.5).

NOTE 2 Generally records need not be under revision control.

3.8 Terms relating to examination

3.8.1
objective evidence
data supporting the existence or verity of something

NOTE Objective evidence may be obtained through observation, measurement, **test** (3.8.3), or other means.

3.8.2
inspection
conformity evaluation by observation and judgement accompanied as appropriate by measurement, testing or gauging

[ISO/IEC Guide 2]

3.8.3
test
determination of one or more **characteristics** (3.5.1) according to a **procedure** (3.4.5)

3.8.4
verification
confirmation, through the provision of **objective evidence** (3.8.1), that specified **requirements** (3.1.2) have been fulfilled

NOTE 1 The term “verified” is used to designate the corresponding status.

NOTE 2 Confirmation can comprise activities such as

— performing alternative calculations,

— comparing a new design **specification** (3.7.3) with a similar proven design specification,

— undertaking **tests** (3.8.3) and demonstrations, and

— reviewing documents prior to issue.

3.8.5
validation
confirmation, through the provision of **objective evidence** (3.8.1), that the **requirements** (3.1.2) for a specific intended use or application have been fulfilled

NOTE 1 The term “validated” is used to designate the corresponding status.

NOTE 2 The use conditions for validation can be real or simulated.

3.8.6
qualification process
process (3.4.1) to demonstrate the ability to fulfil specified **requirements** (3.1.2)

NOTE 1 The term “qualified” is used to designate the corresponding status.

NOTE 2 Qualification can concern persons, **products** (3.4.2), processes or **systems** (3.2.1).

EXAMPLE Auditor qualification process, material qualification process.

3.8.7
review
activity undertaken to determine the suitability, adequacy and **effectiveness** (3.2.14) of the subject matter to achieve established objectives

NOTE Review can also include the determination of **efficiency** (3.2.15).

EXAMPLE Management review, design and development review, review of customer requirements and nonconformity review.

3.9 Terms relating to audit

NOTE The terms and definitions given in 3.9 have been prepared in anticipation of the publication of ISO 19011. It is possible that they will be modified in that standard.

3.9.1
audit
systematic, independent and documented **process** (3.4.1) for obtaining **audit evidence** (3.9.4) and evaluating it objectively to determine the extent to which **audit criteria** (3.9.3) are fulfilled

NOTE Internal audits, sometimes called first-party audits, are conducted by, or on behalf of, the **organization** (3.3.1) itself for internal purposes and can form the basis for an organization’s self-declaration of **conformity** (3.6.1).

External audits include what are generally termed “second-” or “third-party audits”.

Second-party audits are conducted by parties having an interest in the organization, such as customers, or by other persons on their behalf.

Third-party audits are conducted by external independent organizations. Such organizations provide certification or registration of conformity with requirements such as those of ISO 9001 and ISO 14001:1996.

When quality and environmental **management systems** (3.2.2) are audited together, this is termed a “combined audit”.

When two or more auditing organizations cooperate to audit a single **auditee** (3.9.8) jointly, this is termed “joint audit”.

3.9.2
audit programme
set of one or more **audits** (3.9.1) planned for a specific time frame and directed towards a specific purpose

3.9.3
audit criteria
set of policies, **procedures** (3.4.5) or **requirements** (3.1.2) used as a reference

3.9.4
audit evidence
records (3.7.6), statements of fact or other **information** (3.7.1) which are relevant to the **audit criteria** (3.9.3) and verifiable

NOTE Audit evidence can be qualitative or quantitative.

3.9.5
audit findings
results of the evaluation of the collected **audit evidence** (3.9.4) against **audit criteria** (3.9.3)

NOTE Audit findings can indicate either conformity or nonconformity with audit criteria, or opportunities for improvement.

3.9.6
audit conclusion
outcome of an **audit** (3.9.1) provided by the **audit team** (3.9.10) after consideration of the audit objectives and all **audit findings** (3.9.5)

3.9.7
audit client
organization (3.3.1) or person requesting an **audit** (3.9.1)

3.9.8
auditee
organization (3.3.1) being audited

3.9.9
auditor
person with the **competence** (3.9.12) to conduct an **audit** (3.9.1)

3.9.10
audit team
one or more **auditors** (3.9.9) conducting an **audit** (3.9.1)

NOTE 1 One auditor in the audit team is generally appointed as audit team leader.

NOTE 2 The audit team can include auditors-in-training and, where required, **technical experts** (3.9.11).

NOTE 3 Observers can accompany the audit team but do not act as part of it.

3.9.11
technical expert
⟨audit⟩ person who provides specific knowledge of or expertise on the subject to be audited

NOTE 1 Specific knowledge or expertise includes knowledge of or expertise on the **organization** (3.3.1), **process** (3.4.1) or activity to be audited, as well as language or cultural guidance.

NOTE 2 A technical expert does not act as an **auditor** (3.9.9) in the **audit team** (3.9.10).

3.9.12
competence
demonstrated ability to apply knowledge and skills

3.10 Terms related to quality assurance for measurement processes

NOTE The terms and definitions given in 3.10 have been prepared in anticipation of the publication of ISO 10012. It is possible that they will be modified in that standard.

3.10.1
measurement control system
set of interrelated or interacting elements necessary to achieve **metrological confirmation** (3.10.3) and continual control of **measurement processes** (3.10.2)

3.10.2
measurement process
set of operations to determine the value of a quantity

3.10.3
metrological confirmation
set of operations required to ensure that **measuring equipment** (3.10.4) conforms to the **requirements** (3.1.2) for its intended use

NOTE 1 Metrological confirmation generally includes calibration or **verification** (3.8.4), any necessary adjustment or **repair** (3.6.9), and subsequent recalibration, comparison with the metrological requirements for the intended use of the equipment, as well as any required sealing and labelling.

NOTE 2 Metrological confirmation is not achieved until and unless the fitness of the measuring equipment for the intended use has been demonstrated and documented.

NOTE 3 The requirements for the intended use include such considerations as range, resolution, maximum permissible errors, etc.

NOTE 4 Metrological confirmation requirements are usually distinct from and are not specified in product requirements.

3.10.4
measuring equipment
measuring instrument, software, measurement standard, reference material or auxiliary apparatus or combination thereof necessary to realize a **measurement process** (3.10.2)

3.10.5
metrological characteristic
distinguishing feature which can influence the results of measurement

NOTE 1 **Measuring equipment** (3.10.4) usually has several metrological characteristics.

NOTE 2 Metrological characteristics can be the subject of calibration.

3.10.6
metrological function
function with organizational responsibility for defining and implementing the **measurement control system** (3.10.1)

Annex A
(informative)

Methodology used in the development of the vocabulary

A.1 Introduction

The universality of application of the ISO 9000 family of standards requires the use of

— a technical description but without the use of technical language, and

— a coherent and harmonized vocabulary that is easily understandable by all potential users of quality management systems standards.

Concepts are not independent of one another, and an analysis of the relationships between concepts within the field of quality management systems and the arrangement of them into concept systems is a prerequisite of a coherent vocabulary. Such an analysis was used in the development of the vocabulary specified in this International Standard. Since the concept diagrams employed during the development process may be helpful in an informative sense, they are reproduced in A.4.

A.2 Content of a vocabulary entry and the substitution rule

The concept forms the unit of transfer between languages (including variants within one language, for example American English and British English). For each language, the most appropriate term for the universal transparency of the concept in that language, i.e. not a literal approach to translation, is chosen.

A definition is formed by describing only those characteristics that are essential to identify the concept. Information concerning the concept which is important but which is not essential to its description is put in one or more notes to the definition.

When a term is substituted by its definition, subject to minor syntax changes, there should be no change in the meaning of the text. Such a substitution provides a simple method for checking the accuracy of a definition. However, where the definition is complex in the sense that it contains a number of terms, substitution is best carried out taking one or, at most, two definitions at a time. Complete substitution of the totality of the terms will become difficult to achieve syntactically and unhelpful in conveying meaning.

A.3 Concept relationships and their graphical representation

A.3.1 General

In terminology work the relationships between concepts are based on the hierarchical formation of the characteristics of a species so that the most economical description of a concept is formed by naming its species and describing the characteristics that distinguish it from its parent or sibling concepts.

There are three primary forms of concept relationships indicated in this annex: generic (A.3.2), partitive (A.3.3) and associative (A.3.4).

A.3.2 Generic relation

Subordinate concepts within the hierarchy inherit all the characteristics of the superordinate concept and contain descriptions of these characteristics which distinguish them from the superordinate (parent) and coordinate (sibling) concepts, e.g. the relation of spring, summer, autumn and winter to season.

Generic relations are depicted by a fan or tree diagram without arrows (see Figure A.1).

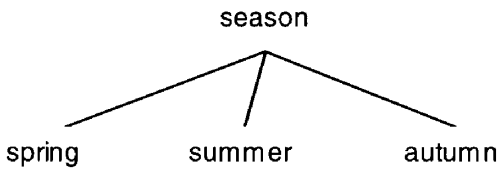


Figure A.1 — Graphical representation of a generic relation

A.3.3 Partitive relation

Subordinate concepts within the hierarchy form constituent parts of the superordinate concept, e.g. spring, summer, autumn and winter may be defined as parts of the concept year. In comparison, it is inappropriate to define sunny weather (one possible characteristic of summer) as part of a year.

Partitive relations are depicted by a rake without arrows (see Figure A.2). Singular parts are depicted by one line, multiple parts by double lines.

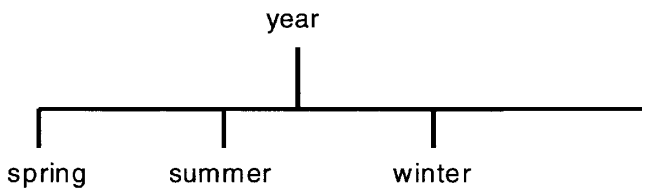


Figure A.2 — Graphical representation of a partitive relation

A.3.4 Associative relation

Associative relations cannot provide the economies in description that are present in generic and partitive relations but are helpful in identifying the nature of the relationship between one concept and another within a concept system, e.g. cause and effect, activity and location, activity and result, tool and function, material and product.

Associative relations are depicted by a line with arrowheads at each end (see Figure A.3).

Figure A.3 — Graphical representation of an associative relation

A.4 Concept diagrams

Figures A.4 to A.13 show the concept diagrams on which the thematic groupings of clause 3 of this International Standard are based.

Although the definitions of the terms are repeated, any related notes are not, and it is recommended to refer to clause 3 to consult any such notes.

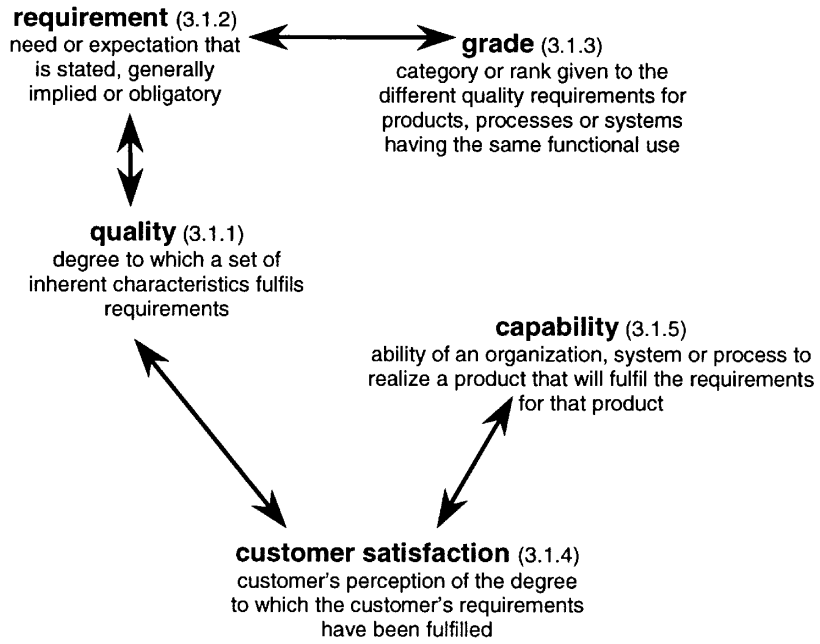


Figure A.4 — Concepts relating to quality (3.1)

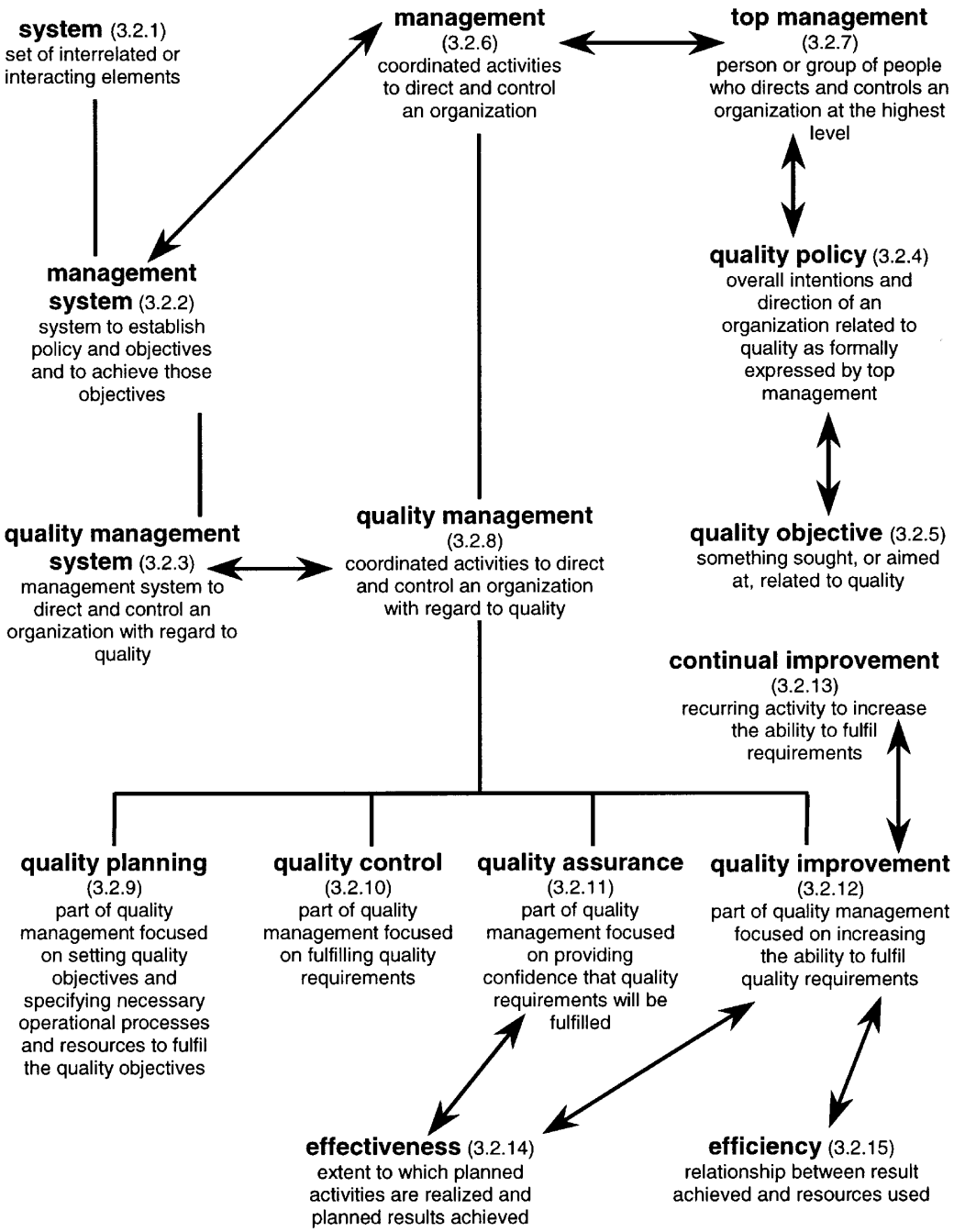


Figure A.5 — Concepts relating to management (3.2)

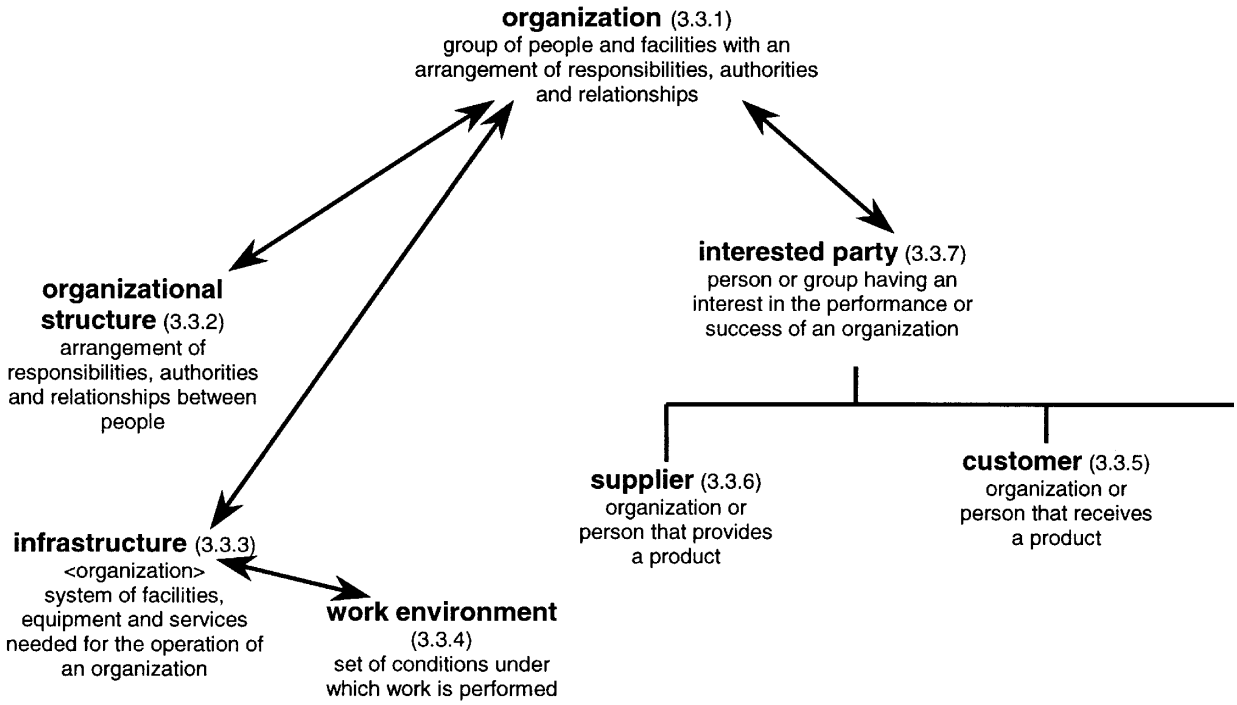


Figure A.6 — Concepts relating to organization (3.3)

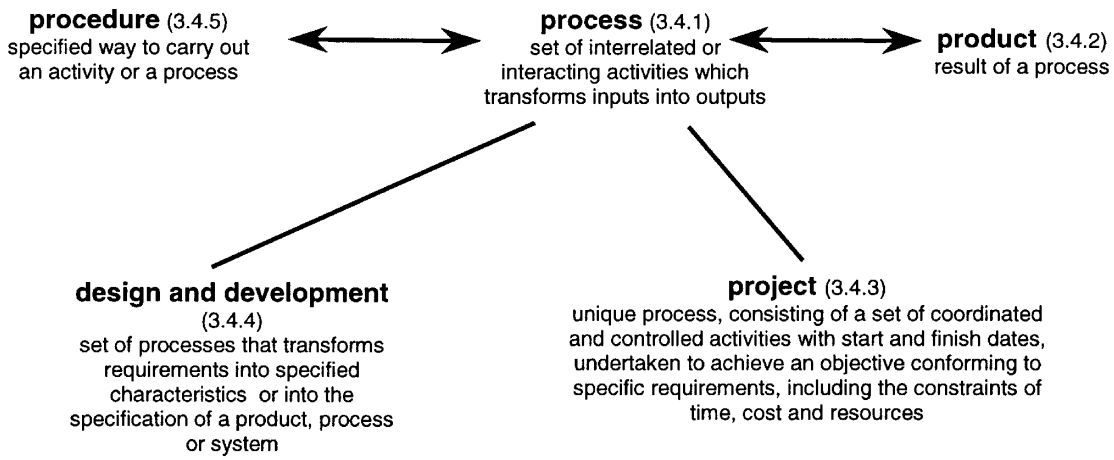


Figure A.7 — Concepts relating to process and product (3.4)

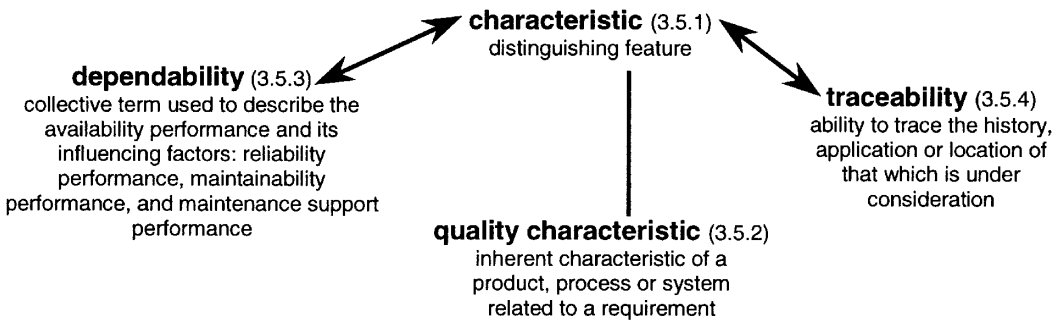


Figure A.8 — Concepts relating to characteristics (3.5)

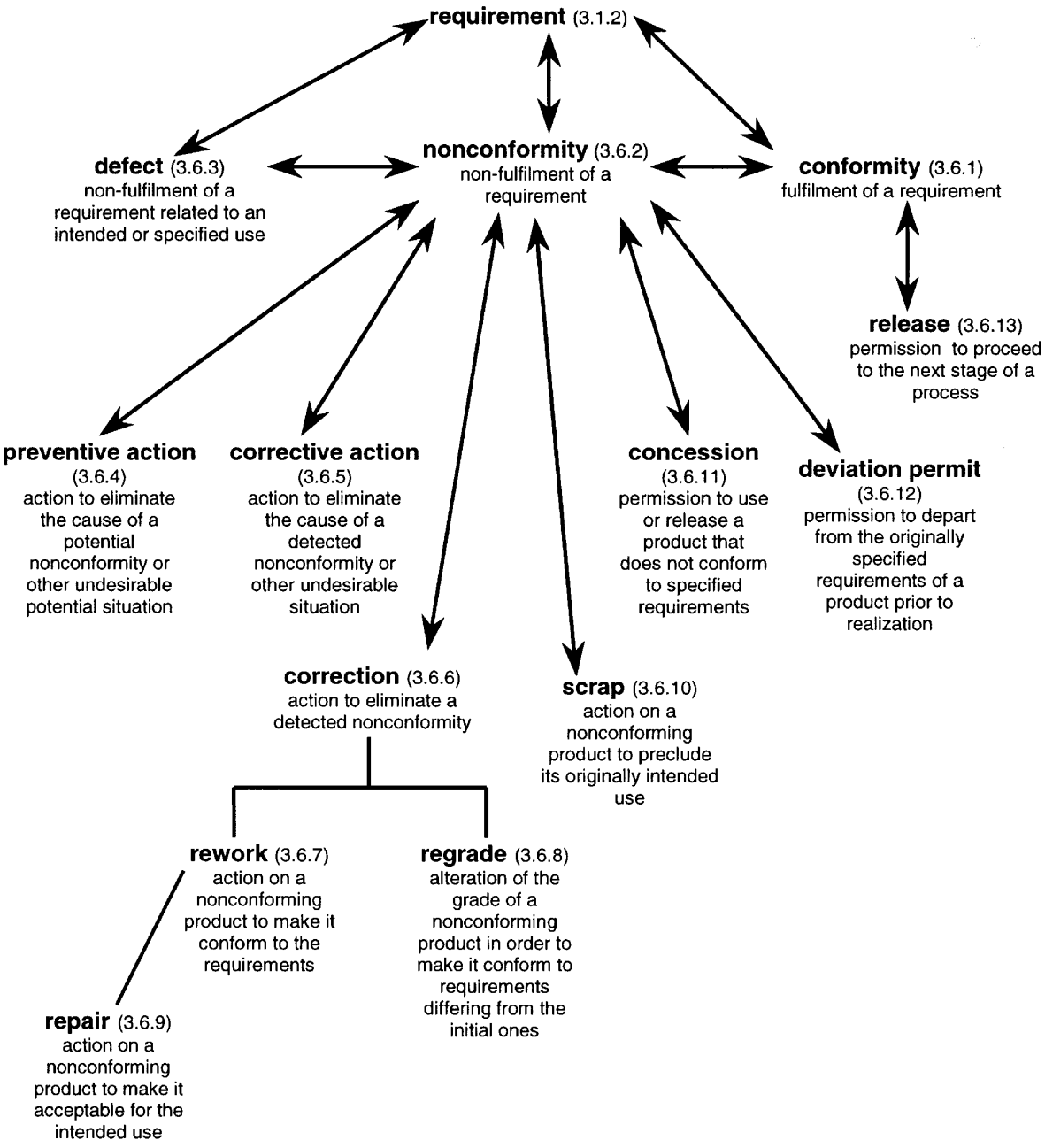


Figure A.9 — Concepts relating to conformity (3.6)

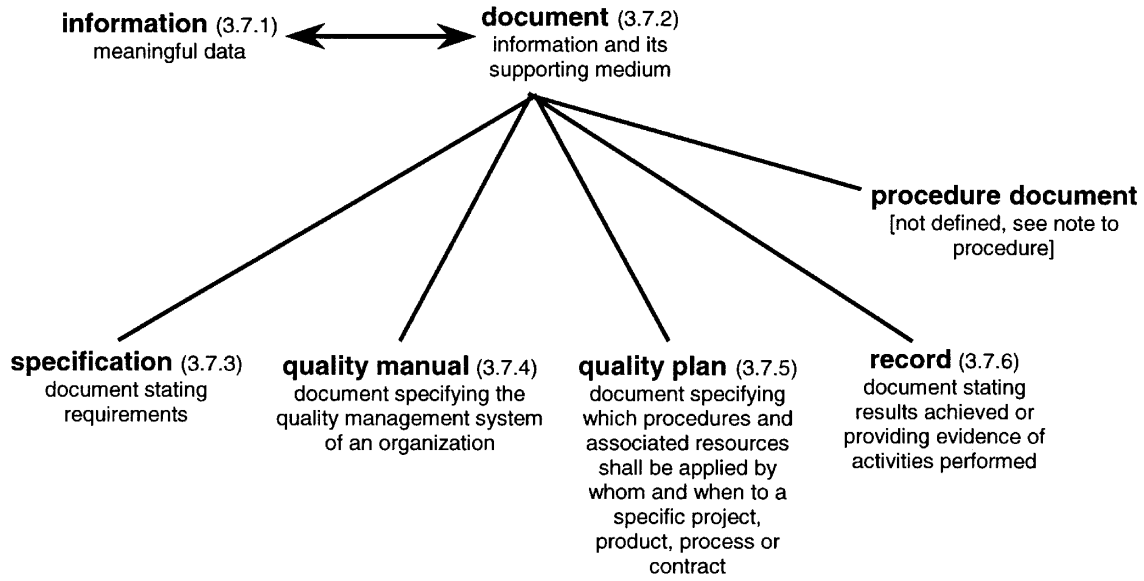


Figure A.10 — Concepts relating to documentation (3.7)

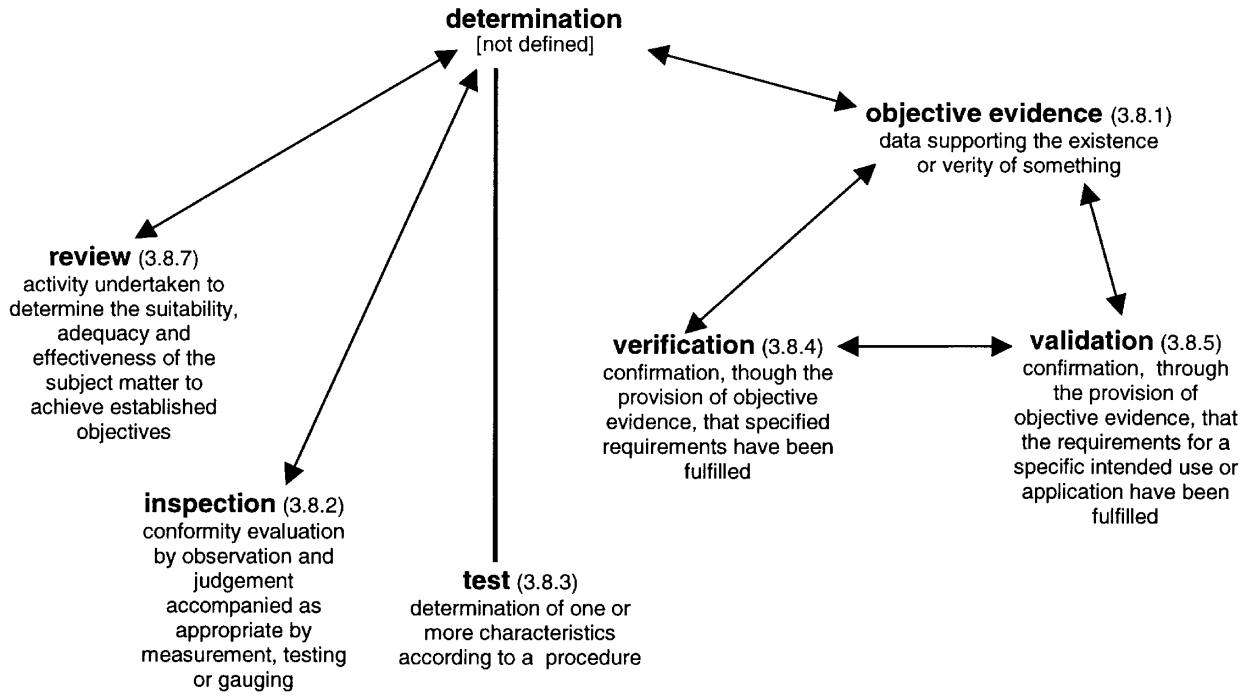


Figure A.11 — Concepts relating to examination (3.8)

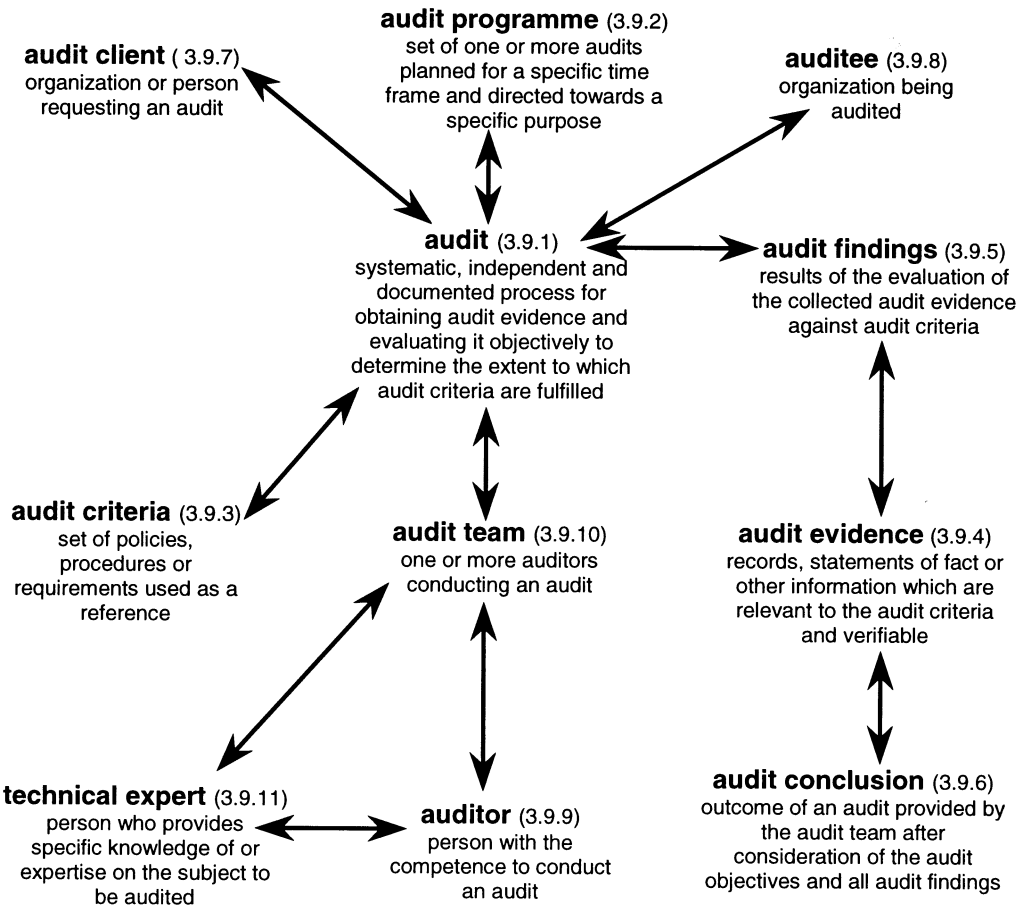


Figure A.12 — Concepts relating to audit (3.9)

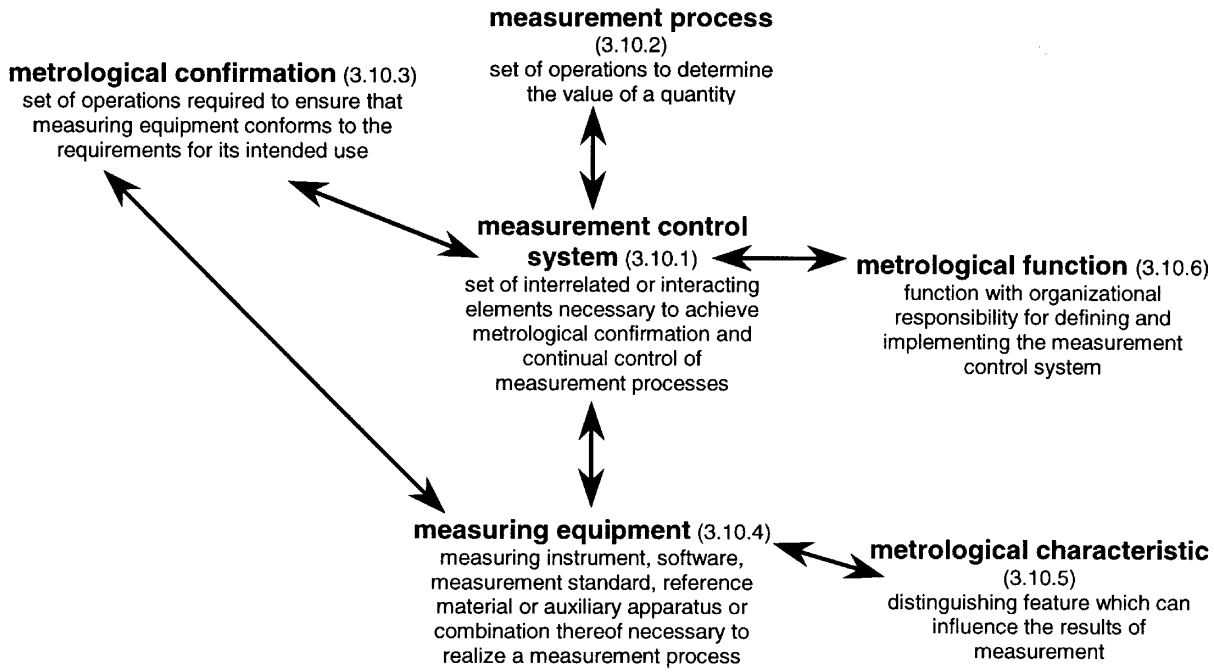


Figure A.13 — Concepts relating to quality assurance for measurement processes (3.10)

Bibliography

[1] ISO/IEC Guide 2, *Standardization and related activities — General vocabulary*.

[2] ISO 704, *Terminology work — Principles and methods*.

[3] ISO 1087-1, *Terminology work — Vocabulary — Part 1: Theory and application*.

[4] ISO 3534-2, *Statistics — Vocabulary and symbols — Part 2: Statistical quality control*.

[5] ISO 9000-1:1994, *Quality management and quality assurance standards — Part 1: Guidelines for selection and use*.

[6] ISO 9001:2000, *Quality management systems — Requirements*.

[7] ISO 9004:2000, *Quality management systems — Guidelines for performance improvements*.

[8] ISO 10006:1997, *Quality management — Guidelines to quality in project management*.

[9] ISO 10012:—[1)], *Quality assurance requirements for measuring equipment*.

[10] ISO 10013:1995, *Guidelines for developing quality manuals*.

[11] ISO/TR 10017, *Guidance on statistical techniques for ISO 9001:1994*.

[12] ISO 10241, *International terminology standards — Preparation and layout*.

[13] ISO/TR 13425, *Guide for the selection of statistical methods in standardization and specification*.

[14] ISO 14001:1996, *Environmental management systems — Specification with guidance for use*.

[15] ISO 19011:—[2)], *Guidelines on quality and/or environmental management systems auditing*.

[16] IEC 60050-191:1990, *International Electrotechnical Vocabulary — Chapter 191: Dependability and quality of service*.

[17] VIM:1993, *International vocabulary of basic and general terms in metrology*. BIPM/IEC/IFCC/ISO/OIML/IUPAC/IUPAP.

[18] *Quality Management Principles Brochure* [3)].

[19] *ISO 9000 + ISO 14000 News* (a bimonthly publication which provides comprehensive coverage of international developments relating to ISO's management system standards, including news of their implementation by diverse organizations around the world) [4)].

1) To be published. (Revision of ISO 10012-1:1992 and ISO 10012-2:1997)

2) To be published.

3) Available from website: http://www.iso.ch

4) Available from ISO Central Secretariat (sales@iso.ch).

Alphabetical index

Additional resources on the ANSI/ISO/ASQ Q9000:2000 Standards available from ASQ Quality Press:

ISO 9001:2000 Explained, Second Edition
Charles A. Cianfrani, Joseph J. Tsiakals, and John E. (Jack) West
http://qualitypress.asq.org/perl/catalog.cgi?item=H1104

The ISO Lesson Guide 2000: Pocket Guide to Q9001:2000, Second Edition
Dennis Arter and J. P. Russell
http://qualitypress.asq.org/perl/catalog.cgi?item=H1102

ISO 9001:2000 – An Audio Workshop and Master Slide Presentation
John E. (Jack) West and Charles A. Cianfrani
http://qualitypress.asq.org/perl/catalog.cgi?item=H1106

ISO 9001:2000 Quick Reference
Jeanne Ketola and Kathy Roberts
http://qualitypress.asq.org/perl/catalog.cgi?item=H1107

ISO 9000 at the Front Line
William A. Levinson
http://qualitypress.asq.org/perl/catalog.cgi?item=H0987

After the Quality Audit: Closing the Loop on the Audit Process, Second Edition
J. P. Russell and Terry Regel
http://qualitypress.asq.org/perl/catalog.cgi?item=H1070

Internal Quality Auditing
Denis Pronovost
http://qualitypress.asq.org/perl/catalog.cgi?item=H1069

Quality Press has created an ISO 9000:2000 Resource Materials web page. This convenient online resource contains links to all the books, journals, standards, and courses that are available through ASQ (as well as general information and FAQs) on this important revision to the standards. You can visit this page from our Online Bookstore at http://qualitypress.asq.org.

To request a complimentary catalog of ASQ Quality Press publications, call 800-248-1946, or visit our Online Bookstore at http://qualitypress.asq.org.

American Society for Quality

Quality Press
P.O. Box 3005
Milwaukee, Wisconsin 53201-3005
800-248-1946
Fax 414-272-1734
www.asq.org
http://qualitypress.asq.org
http://standardsgroup.asq.org

T2110E

AMERICAN NATIONAL STANDARD

Quality management systems— Requirements

Approved as a American National Standard by:
American Society for Quality

An American National Standard Approved on December 13, 2000

Note: As used in this document, the term "International Standard" refers to the American National Standard adoption of this and other International Standards.

ASQ will consider requests for change and information on the submittal of such requests regarding this Standard. All requests should be in writing to the attention of the Standards administrator at the address below.

ASQ Mission: The American Society for Quality advances individual and organizational performance excellence worldwide by providing opportunities for learning, quality improvement, and knowledge exchange.

Published by:

American Society for Quality

ASQ

Quality Press
P.O. Box 3005
Milwaukee, Wisconsin 53201-3005
800-248-1946
Fax 414-272-1734
www.asq.org
http://qualitypress.asq.org
http://standardsgroup.asq.org

Contents

Page

Annexes

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 9001 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 2, *Quality systems*.

This third edition of ISO 9001 cancels and replaces the second edition (ISO 9001:1994) together with ISO 9002:1994 and ISO 9003:1994. It constitutes a technical revision of these documents. Those organizations which have used ISO 9002:1994 and ISO 9003:1994 in the past may use this International Standard by excluding certain requirements in accordance with 1.2.

The title of ISO 9001 has been revised in this edition and no longer includes the term “Quality assurance”. This reflects the fact that the quality management system requirements specified in this edition of ISO 9001, in addition to quality assurance of product, also aim to enhance customer satisfaction.

Annexes A and B of this International Standard are for information only.

Introduction

0.1 General

The adoption of a quality management system should be a strategic decision of an organization. The design and implementation of an organization's quality management system is influenced by varying needs, particular objectives, the products provided, the processes employed and the size and structure of the organization. It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

The quality management system requirements specified in this International Standard are complementary to requirements for products. Information marked “NOTE” is for guidance in understanding or clarifying the associated requirement.

This International Standard can be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer, regulatory and the organization's own requirements.

The quality management principles stated in ISO 9000 and ISO 9004 have been taken into consideration during the development of this International Standard.

0.2 Process approach

This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements.

For an organization to function effectively, it has to identify and manage numerous linked activities. An activity using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process. Often the output from one process directly forms the input to the next.

The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management, can be referred to as the “process approach”.

An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction.

When used within a quality management system, such an approach emphasizes the importance of

a) understanding and meeting requirements,

b) the need to consider processes in terms of added value,

c) obtaining results of process performance and effectiveness, and

d) continual improvement of processes based on objective measurement.

The model of a process-based quality management system shown in Figure 1 illustrates the process linkages presented in clauses 4 to 8. This illustration shows that customers play a significant role in defining requirements as inputs. Monitoring of customer satisfaction requires the evaluation of information relating to customer perception as to whether the organization has met the customer requirements. The model shown in Figure 1 covers all the requirements of this International Standard, but does not show processes at a detailed level.

NOTE In addition, the methodology known as “Plan-Do-Check-Act” (PDCA) can be applied to all processes. PDCA can be briefly described as follows.

Plan: establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization's policies.

Do: implement the processes.

Check: monitor and measure processes and product against policies, objectives and requirements for the product and report the results.

Act: take actions to continually improve process performance.

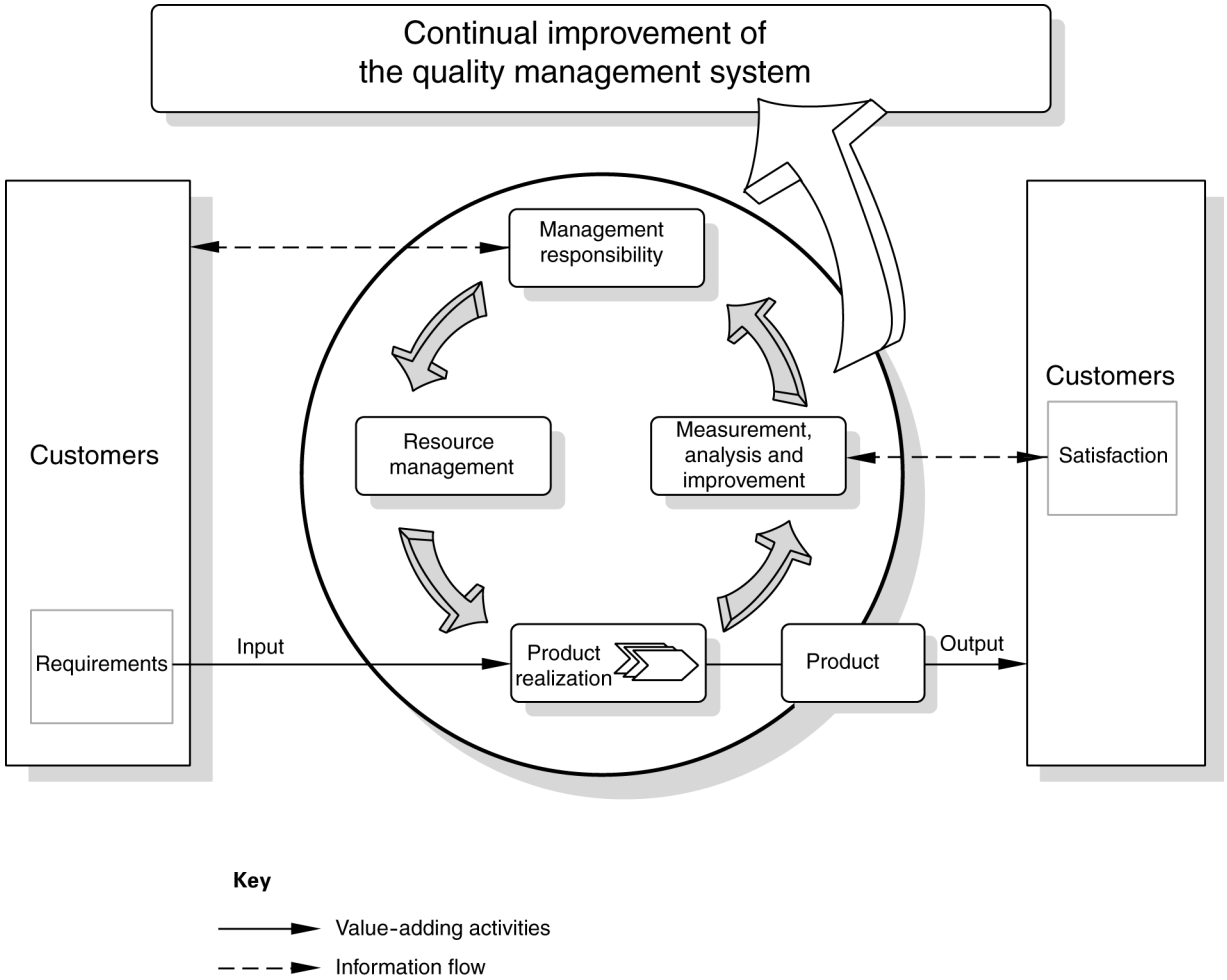


Figure 1 — Model of a process-based quality management system

0.3 Relationship with ISO 9004

The present editions of ISO 9001 and ISO 9004 have been developed as a consistent pair of quality management system standards which have been designed to complement each other, but can also be used independently. Although the two International Standards have different scopes, they have similar structures in order to assist their application as a consistent pair.

ISO 9001 specifies requirements for a quality management system that can be used for internal application by organizations, or for certification, or for contractual purposes. It focuses on the effectiveness of the quality management system in meeting customer requirements.

ISO 9004 gives guidance on a wider range of objectives of a quality management system than does ISO 9001, particularly for the continual improvement of an organization's overall performance and efficiency, as well as its effectiveness. ISO 9004 is recommended as a guide for organizations whose top management wishes to move beyond the requirements of ISO 9001, in pursuit of continual improvement of performance. However, it is not intended for certification or for contractual purposes.

0.4 Compatibility with other management systems

This International Standard has been aligned with ISO 14001:1996 in order to enhance the compatibility of the two standards for the benefit of the user community.

This International Standard does not include requirements specific to other management systems, such as those particular to environmental management, occupational health and safety management, financial management or risk management. However, this International Standard enables an organization to align or integrate its own quality management system with related management system requirements. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that complies with the requirements of this International Standard.

Quality management systems — Requirements

1 Scope

1.1 General

This International Standard specifies requirements for a quality management system where an organization

a) needs to demonstrate its ability to consistently provide product that meets customer and applicable regulatory requirements, and

b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable regulatory requirements.

NOTE In this International Standard, the term “product” applies only to the product intended for, or required by, a customer.

1.2 Application

All requirements of this International Standard are generic and are intended to be applicable to all organizations, regardless of type, size and product provided.

Where any requirement(s) of this International Standard cannot be applied due to the nature of an organization and its product, this can be considered for exclusion.

Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within clause 7, and such exclusions do not affect the organization's ability, or responsibility, to provide product that meets customer and applicable regulatory requirements.

2 Normative reference

The following normative document contains provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 9000:2000, *Quality management systems — Fundamentals and vocabulary*.

3 Terms and definitions

For the purposes of this International Standard, the terms and definitions given in ISO 9000 apply.

The following terms, used in this edition of ISO 9001 to describe the supply chain, have been changed to reflect the vocabulary currently used:

supplier → **organization** → **customer**

The term “organization” replaces the term “supplier” used in ISO 9001:1994, and refers to the unit to which this International Standard applies. Also, the term “supplier” now replaces the term “subcontractor”.

Throughout the text of this International Standard, wherever the term “product” occurs, it can also mean “service”.

4 Quality management system

4.1 General requirements

The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.

The organization shall

a) identify the processes needed for the quality management system and their application throughout the organization (see 1.2),

b) determine the sequence and interaction of these processes,

c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,

d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,

e) monitor, measure and analyse these processes, and

f) implement actions necessary to achieve planned results and continual improvement of these processes.

These processes shall be managed by the organization in accordance with the requirements of this International Standard.

Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system.

NOTE Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement.

4.2 Documentation requirements

4.2.1 General

The quality management system documentation shall include

a) documented statements of a quality policy and quality objectives,

b) a quality manual,

c) documented procedures required by this International Standard,

d) documents needed by the organization to ensure the effective planning, operation and control of its processes, and

e) records required by this International Standard (see 4.2.4).

NOTE 1 Where the term “documented procedure” appears within this International Standard, this means that the procedure is established, documented, implemented and maintained.

NOTE 2 The extent of the quality management system documentation can differ from one organization to another due to

a) the size of organization and type of activities,

b) the complexity of processes and their interactions, and

c) the competence of personnel.

NOTE 3 The documentation can be in any form or type of medium.

4.2.2 Quality manual

The organization shall establish and maintain a quality manual that includes

a) the scope of the quality management system, including details of and justification for any exclusions (see 1.2),

b) the documented procedures established for the quality management system, or reference to them, and

c) a description of the interaction between the processes of the quality management system.

4.2.3 Control of documents

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

A documented procedure shall be established to define the controls needed

a) to approve documents for adequacy prior to issue,

b) to review and update as necessary and re-approve documents,

c) to ensure that changes and the current revision status of documents are identified,

d) to ensure that relevant versions of applicable documents are available at points of use,

e) to ensure that documents remain legible and readily identifiable,

f) to ensure that documents of external origin are identified and their distribution controlled, and

g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

4.2.4 Control of records

Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

5 Management responsibility

5.1 Management commitment

Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by

a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,

b) establishing the quality policy,

c) ensuring that quality objectives are established,

d) conducting management reviews, and

e) ensuring the availability of resources.

5.2 Customer focus

Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1).

5.3 Quality policy

Top management shall ensure that the quality policy

a) is appropriate to the purpose of the organization,

b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system,

c) provides a framework for establishing and reviewing quality objectives,

d) is communicated and understood within the organization, and

e) is reviewed for continuing suitability.

5.4 Planning

5.4.1 Quality objectives

Top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1 a)], are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

5.4.2 Quality management system planning

Top management shall ensure that

a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and

b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

Top management shall ensure that responsibilities and authorities are defined and communicated within the organization.

5.5.2 Management representative

Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes

a) ensuring that processes needed for the quality management system are established, implemented and maintained,

b) reporting to top management on the performance of the quality management system and any need for improvement, and

c) ensuring the promotion of awareness of customer requirements throughout the organization.

NOTE The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.

5.5.3 Internal communication

Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

5.6 Management review

5.6.1 General

Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews shall be maintained (see 4.2.4).

5.6.2 Review input

The input to management review shall include information on

a) results of audits,

b) customer feedback,

c) process performance and product conformity,

d) status of preventive and corrective actions,

e) follow-up actions from previous management reviews,

f) changes that could affect the quality management system, and

g) recommendations for improvement.

5.6.3 Review output

The output from the management review shall include any decisions and actions related to

a) improvement of the effectiveness of the quality management system and its processes,

b) improvement of product related to customer requirements, and

c) resource needs.

6 Resource management

6.1 Provision of resources

The organization shall determine and provide the resources needed

a) to implement and maintain the quality management system and continually improve its effectiveness, and

b) to enhance customer satisfaction by meeting customer requirements.

6.2 Human resources

6.2.1 General

Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.

6.2.2 Competence, awareness and training

The organization shall

a) determine the necessary competence for personnel performing work affecting product quality,

b) provide training or take other actions to satisfy these needs,

c) evaluate the effectiveness of the actions taken,

d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and

e) maintain appropriate records of education, training, skills and experience (see 4.2.4).

6.3 Infrastructure

The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable

a) buildings, workspace and associated utilities,

b) process equipment (both hardware and software), and

c) supporting services (such as transport or communication).

6.4 Work environment

The organization shall determine and manage the work environment needed to achieve conformity to product requirements.

7 Product realization

7.1 Planning of product realization

The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1).

In planning product realization, the organization shall determine the following, as appropriate:

a) quality objectives and requirements for the product;

b) the need to establish processes, documents, and provide resources specific to the product;

c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;

d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).

The output of this planning shall be in a form suitable for the organization's method of operations.

NOTE 1 A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan.

NOTE 2 The organization may also apply the requirements given in 7.3 to the development of product realization processes.

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

The organization shall determine

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,

b) requirements not stated by the customer but necessary for specified or intended use, where known,

c) statutory and regulatory requirements related to the product, and

d) any additional requirements determined by the organization.

7.2.2 Review of requirements related to the product

The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that

a) product requirements are defined,

b) contract or order requirements differing from those previously expressed are resolved, and

c) the organization has the ability to meet the defined requirements.

Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.

Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material.

7.2.3 Customer communication

The organization shall determine and implement effective arrangements for communicating with customers in relation to

a) product information,

b) enquiries, contracts or order handling, including amendments, and

c) customer feedback, including customer complaints.

7.3 Design and development

7.3.1 Design and development planning

The organization shall plan and control the design and development of product.

During the design and development planning, the organization shall determine

a) the design and development stages,

b) the review, verification and validation that are appropriate to each design and development stage, and

c) the responsibilities and authorities for design and development.

The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output shall be updated, as appropriate, as the design and development progresses.

7.3.2 Design and development inputs

Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include

a) functional and performance requirements,

b) applicable statutory and regulatory requirements,

c) where applicable, information derived from previous similar designs, and

d) other requirements essential for design and development.

These inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.

7.3.3 Design and development outputs

The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release.

Design and development outputs shall

a) meet the input requirements for design and development,

b) provide appropriate information for purchasing, production and for service provision,

c) contain or reference product acceptance criteria, and

d) specify the characteristics of the product that are essential for its safe and proper use.

7.3.4 Design and development review

At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1)

a) to evaluate the ability of the results of design and development to meet requirements, and

b) to identify any problems and propose necessary actions.

Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4).

7.3.5 Design and development verification

Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4).

7.3.6 Design and development validation

Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (see 4.2.4).

7.3.7 Control of design and development changes

Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered.

Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).

7.4 Purchasing

7.4.1 Purchasing process

The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.

The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).

7.4.2 Purchasing information

Purchasing information shall describe the product to be purchased, including where appropriate

a) requirements for approval of product, procedures, processes and equipment,

b) requirements for qualification of personnel, and

c) quality management system requirements.

The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

7.4.3 Verification of purchased product

The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.

7.5 Production and service provision

7.5.1 Control of production and service provision

The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable

a) the availability of information that describes the characteristics of the product,

b) the availability of work instructions, as necessary,

c) the use of suitable equipment,

d) the availability and use of monitoring and measuring devices,

e) the implementation of monitoring and measurement, and

f) the implementation of release, delivery and post-delivery activities.

7.5.2 Validation of processes for production and service provision

The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.

Validation shall demonstrate the ability of these processes to achieve planned results.

The organization shall establish arrangements for these processes including, as applicable

a) defined criteria for review and approval of the processes,

b) approval of equipment and qualification of personnel,

c) use of specific methods and procedures,

d) requirements for records (see 4.2.4), and

e) revalidation.

7.5.3 Identification and traceability

Where appropriate, the organization shall identify the product by suitable means throughout product realization.

The organization shall identify the product status with respect to monitoring and measurement requirements.

Where traceability is a requirement, the organization shall control and record the unique identification of the product (see 4.2.4).

NOTE In some industry sectors, configuration management is a means by which identification and traceability are maintained.

7.5.4 Customer property

The organization shall exercise care with customer property while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained (see 4.2.4).

NOTE Customer property can include intellectual property.

7.5.5 Preservation of product

The organization shall preserve the conformity of product during internal processing and delivery to the intended destination. This preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

7.6 Control of monitoring and measuring devices

The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1).

The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment shall

a) be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded;

b) be adjusted or re-adjusted as necessary;

c) be identified to enable the calibration status to be determined;

d) be safeguarded from adjustments that would invalidate the measurement result;

e) be protected from damage and deterioration during handling, maintenance and storage.

In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained (see 4.2.4).

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

NOTE See ISO 10012-1 and ISO 10012-2 for guidance.

8 Measurement, analysis and improvement

8.1 General

The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed

a) to demonstrate conformity of the product,

b) to ensure conformity of the quality management system, and

c) to continually improve the effectiveness of the quality management system.

This shall include determination of applicable methods, including statistical techniques, and the extent of their use.

8.2 Monitoring and measurement

8.2.1 Customer satisfaction

As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.

8.2.2 Internal audit

The organization shall conduct internal audits at planned intervals to determine whether the quality management system

a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and

b) is effectively implemented and maintained.

An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) shall be defined in a documented procedure.

The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).

NOTE See ISO 10011-1, ISO 10011-2 and ISO 10011-3 for guidance.

8.2.3 Monitoring and measurement of processes

The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.

8.2.4 Monitoring and measurement of product

The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1).

Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see 4.2.4).

Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

8.3 Control of nonconforming product

The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure.

The organization shall deal with nonconforming product by one or more of the following ways:

a) by taking action to eliminate the detected nonconformity;

b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;

c) by taking action to preclude its original intended use or application.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).

When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.

When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity.

8.4 Analysis of data

The organization shall determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data shall provide information relating to

a) customer satisfaction (see 8.2.1),

b) conformity to product requirements (see 7.2.1),

c) characteristics and trends of processes and products including opportunities for preventive action, and

d) suppliers.

8.5 Improvement

8.5.1 Continual improvement

The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

8.5.2 Corrective action

The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

A documented procedure shall be established to define requirements for

a) reviewing nonconformities (including customer complaints),

b) determining the causes of nonconformities,

c) evaluating the need for action to ensure that nonconformities do not recur,

d) determining and implementing action needed,

e) records of the results of action taken (see 4.2.4), and

f) reviewing corrective action taken.

8.5.3 Preventive action

The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

A documented procedure shall be established to define requirements for

a) determining potential nonconformities and their causes,
b) evaluating the need for action to prevent occurrence of nonconformities,
c) determining and implementing action needed,
d) records of results of action taken (see 4.2.4), and
e) reviewing preventive action taken.

Annex A
(informative)

Correspondence between ISO 9001:2000 and ISO 14001:1996

Table A.1 — Correspondence between ISO 9001:2000 and ISO 14001:1996

ISO 9001:2000		ISO 14001:1996	
Introduction			**Introduction**
General	0.1		
Process approach	0.2		
Relationship with ISO 9004	0.3		
Compatibility with other management systems	0.4		
Scope	**1**	**1**	**Scope**
General	1.1		
Application	1.2		
Normative reference	**2**	**2**	**Normative references**
Terms and definitions	**3**	**3**	**Definitions**
Quality management system	**4**	**4**	**Environmental management system requirements**
General requirements	4.1	4.1	General requirements
Documentation requirements	4.2		
General	4.2.1	4.4.4	Environmental management system documentation
Quality manual	4.2.2	4.4.4	Environmental management system documentation
Control of documents	4.2.3	4.4.5	Document control
Control of records	4.2.4	4.5.3	Records
Management responsibility	**5**	4.4.1	Structure and responsibility
Management commitment	5.1	4.2 4.4.1	Environmental policy Structure and responsibility
Customer focus	5.2	4.3.1 4.3.2	Environmental aspects Legal and other requirements
Quality policy	5.3	4.2	Environmental policy
Planning	5.4	4.3	Planning
Quality objectives	5.4.1	4.3.3	Objectives and targets
Quality management system planning	5.4.2	4.3.4	Environmental management programme(s)
Responsibility, authority and communication	5.5	4.1	General requirements
Responsibility and authority	5.5.1	4.4.1	Structure and responsibility
Management representative	5.5.2		
Internal communication	5.5.3	4.4.3	Communication
Management review	5.6	4.6	Management review
General	5.6.1		
Review input	5.6.2		
Review output	5.6.3		
Resource management	**6**	4.4.1	Structure and responsibility
Provision of resources	6.1		
Human resources	6.2		
General	6.2.1		
Competence, awareness and training	6.2.2	4.4.2	Training, awareness and competence
Infrastructure	6.3	4.4.1	Structure and responsibility
Work environment	6.4		

Table A.1 — Correspondence between ISO 9001:2000 and ISO 14001:1996 (*continued*)

ISO 9001:2000		ISO 14001:1996	
Product realization	**7**	4.4 4.4.6	Implementation and operation Operational control
Planning of product realization	7.1	4.4.6	Operational control
Customer-related processes	7.2		
Determination of requirements related to the product	7.2.1	4.3.1 4.3.2 4.4.6	Environmental aspects Legal and other requirements Operational control
Review of requirements related to the product	7.2.2	4.4.6 4.3.1	Operational control Environmental aspects
Customer communication	7.2.3	4.4.3	Communications
Design and development	7.3		
Design and development planning	7.3.1	4.4.6	Operational control
Design and development inputs	7.3.2		
Design and development outputs	7.3.3		
Design and development review	7.3.4		
Design and development verification	7.3.5		
Design and development validation	7.3.6		
Control of design and development changes	7.3.7		
Purchasing	7.4	4.4.6	Operational control
Purchasing process	7.4.1		
Purchasing information	7.4.2		
Verification of purchased product	7.4.3		
Production and service provision	7.5	4.4.6	Operational control
Control of production and service provision	7.5.1		
Validation of processes for production and service provision	7.5.2		
Identification and traceability	7.5.3		
Customer property	7.5.4		
Preservation of product	7.5.5		
Control of monitoring and measuring devices	7.6	4.5.1	Monitoring and measurement
Measurement, analysis and improvement	**8**	4.5	Checking and corrective action
General	8.1	4.5.1	Monitoring and measurement
Monitoring and measurement	8.2		
Customer satisfaction	8.2.1		
Internal audit	8.2.2	4.5.4	Environmental management system audit
Monitoring and measurement of processes	8.2.3	4.5.1	Monitoring and measurement
Monitoring and measurement of product	8.2.4		
Control of nonconforming product	8.3	4.5.2 4.4.7	Nonconformance and corrective and preventive action Emergency preparedness and response
Analysis of data	8.4	4.5.1	Monitoring and measurement
Improvement	8.5	4.2	Environmental policy
Continual improvement	8.5.1	4.3.4	Environmental management programme(s)
Corrective action	8.5.2	4.5.2	Nonconformance and corrective and preventive action
Preventive action	8.5.3		

Table A.2 — Correspondence between ISO 14001:1996 and ISO 9001:2000

ISO 14001:1996		ISO 9001:2000	
Introduction	—	**0**	**Introduction**
		0.1	General
		0.2	Process approach
		0.3	Relationship with ISO 9004
		0.4	Compatibility with other management systems
Scope	**1**	**1**	**Scope**
		1.1	General
		1.2	Application
Normative references	**2**	**2**	**Normative reference**
Definitions	**3**	**3**	**Terms and definitions**
Environmental management system requirements	**4**	**4**	**Quality management system**
General requirements	4.1	4.1	General requirements
		5.5	Responsibility, authority and communication
		5.5.1	Responsibility and authority
Environmental policy	4.2	5.1	Management commitment
		5.3	Quality policy
		8.5	Improvement
Planning	4.3	5.4	Planning
Environmental aspects	4.3.1	5.2	Customer focus
		7.2.1	Determination of requirements related to the product
		7.2.2	Review of requirements related to the product
Legal and other requirements	4.3.2	5.2	Customer focus
		7.2.1	Determination of requirements related to the product
Objectives and targets	4.3.3	5.4.1	Quality objectives
Environmental management programme(s)	4.3.4	5.4.2	Quality management system planning
		8.5.1	Continual improvement
Implementation and operation	4.4	**7**	**Product realization**
		7.1	Planning of product realization
Structure and responsibility	4.4.1	**5**	**Management responsibility**
		5.1	Management commitment
		5.5.1	Responsibility and authority
		5.5.2	Management representative
		6	**Resource management**
		6.1	Provision of resources
		6.2	Human resources
		6.2.1	General
		6.3	Infrastructure
		6.4	Work environment
Training, awareness and competence	4.4.2	6.2.2	Competence, awareness and training
Communication	4.4.3	5.5.3	Internal communication
		7.2.3	Customer communication
Environmental management system documentation	4.4.4	4.2	Documentation requirements
		4.2.1	General
		4.2.2	Quality manual

Table A.2 — Correspondence between ISO 14001:1996 and ISO 9001:2000 (*continued*)

ISO 14001:1996		ISO 9001:2000	
Document control	4.4.5	4.2.3	Control of documents
Operational control	4.4.6	**7**	**Product realization**
		7.1	Planning of product realization
		7.2	Customer-related processes
		7.2.1	Determination of requirements related to the product
		7.2.2	Review of requirements related to the product
		7.3	Design and development
		7.3.1	Design and development planning
		7.3.2	Design and development inputs
		7.3.3	Design and development outputs
		7.3.4	Design and development review
		7.3.5	Design and development verification
		7.3.6	Design and development validation
		7.3.7	Control of design and development changes
		7.4	Purchasing
		7.4.1	Purchasing process
		7.4.2	Purchasing information
		7.4.3	Verification of purchased product
		7.5	Production and service provision
		7.5.1	Control of production and service provision
		7.5.3	Identification and traceability
		7.5.4	Customer property
		7.5.5	Preservation of product
		7.5.2	Validation of processes for production and service provision
Emergency preparedness and response	4.4.7	8.3	Control of nonconforming product
Checking and corrective action	4.5	**8**	**Measurement, analysis and improvement**
Monitoring and measurement	4.5.1	7.6	Control of monitoring and measuring devices
		8.1	General
		8.2	Monitoring and measurement
		8.2.1	Customer satisfaction
		8.2.3	Monitoring and measurement of processes
		8.2.4	Monitoring and measurement of product
		8.4	Analysis of data
Nonconformance and corrective and preventive action	4.5.2	8.3	Control of nonconforming product
		8.5.2	Corrective action
		8.5.3	Preventive action
Records	4.5.3	4.2.4	Control of records
Environmental management system audit	4.5.4	8.2.2	Internal audit
Management review	4.6	5.6	Management review
		5.6.1	General
		5.6.2	Review input
		5.6.3	Review output

Annex B
(informative)

Correspondence between ISO 9001:2000 and ISO 9001:1994

Table B.1 — Correspondence between ISO 9001:1994 and ISO 9001:2000

ISO 9001:1994	ISO 9001:2000
1 Scope	**1**
2 Normative reference	**2**
3 Definitions	**3**
4 Quality system requirements [title only]	
4.1 Management responsibility [title only]	
4.1.1 Quality policy	5.1 + 5.3 + 5.4.1
4.1.2 Organization [title only]	
4.1.2.1 Responsibility and authority	5.5.1
4.1.2.2 Resources	6.1 + 6.2.1
4.1.2.3 Management representative	5.5.2
4.1.3 Management review	5.6.1 + 8.5.1
4.2 Quality system [title only]	
4.2.1 General	4.1 + 4.2.2
4.2.2 Quality system procedures	4.2.1
4.2.3 Quality planning	5.4.2 + 7.1
4.3 Contract review [title only]	
4.3.1 General	
4.3.2 Review	5.2 + 7.2.1 + 7.2.2 + 7.2.3
4.3.3 Amendment to a contract	7.2.2
4.3.4 Records	7.2.2
4.4 Design control [title only]	
4.4.1 General	
4.4.2 Design and development planning	7.3.1
4.4.3 Organizational and technical interfaces	7.3.1
4.4.4 Design input	7.2.1 + 7.3.2
4.4.5 Design output	7.3.3
4.4.6 Design review	7.3.4
4.4.7 Design verification	7.3.5
4.4.8 Design validation	7.3.6
4.4.9 Design changes	7.3.7
4.5 Document and data control [title only]	
4.5.1 General	4.2.3
4.5.2 Document and data approval and issue	4.2.3
4.5.3 Document and data changes	4.2.3
4.6 Purchasing [title only]	
4.6.1 General	
4.6.2 Evaluation of subcontractors	7.4.1
4.6.3 Purchasing data	7.4.2
4.6.4 Verification of purchased product	7.4.3

Table B.1 — Correspondence between ISO 9001:1994 and ISO 9001:2000 (*continued*)

ISO 9001:1994	ISO 9001:2000
4.7 Control of customer-supplied product	7.5.4
4.8 Product identification and traceability	7.5.3
4.9 Process control	6.3 + 6.4 + 7.5.1 + 7.5.2
4.10 Inspection and testing [title only]	
4.10.1 General	7.1 + 8.1
4.10.2 Receiving inspection and testing	7.4.3 + 8.2.4
4.10.3 In-process inspection and testing	8.2.4
4.10.4 Final inspection and testing	8.2.4
4.10.5 Inspection and test records	7.5.3 + 8.2.4
4.11 Control of inspection, measuring and test equipment [title only]	
4.11.1 General	7.6
4.11.2 Control procedure	7.6
4.12 Inspection and test status	7.5.3
4.13 Control of nonconforming product [title only]	
4.13.1 General	8.3
4.13.2 Review and disposition of nonconforming product	8.3
4.14 Corrective and preventive action [title only]	
4.14.1 General	8.5.2 + 8.5.3
4.14.2 Corrective action	8.5.2
4.14.3 Preventive action	8.5.3
4.15 Handling, storage, packaging, preservation & delivery [title only]	
4.15.1 General	
4.15.2 Handling	7.5.5
4.15.3 Storage	7.5.5
4.15.4 Packaging	7.5.5
4.15.5 Preservation	7.5.5
4.15.6 Delivery	7.5.1
4.16 Control of quality records	4.2.4
4.17 Internal quality audits	8.2.2 + 8.2.3
4.18 Training	6.2.2
4.19 Servicing	7.5.1
4.20 Statistical techniques [title only]	
4.20.1 Identification of need	8.1 + 8.2.3 + 8.2.4 + 8.4
4.20.2 Procedures	8.1 + 8.2.3 + 8.2.4 + 8.4

Table B.2 — Correspondence between ISO 9001:2000 and ISO 9001:1994

ISO 9001:2000	ISO 9001:1994
1 Scope	**1**
1.1 General	
1.2 Application	
2 Normative reference	**2**
3 Terms and definitions	**3**
4 Quality management system [title only]	
4.1 General requirements	4.2.1
4.2 Documentation requirements [title only]	
4.2.1 General	4.2.2
4.2.2 Quality manual	4.2.1
4.2.3 Control of documents	4.5.1 + 4.5.2 + 4.5.3
4.2.4 Control of records	4.16
5 Management responsibility [title only]	
5.1 Management commitment	4.1.1
5.2 Customer focus	4.3.2
5.3 Quality policy	4.1.1
5.4 Planning [title only]	
5.4.1 Quality objectives	4.1.1
5.4.2 Quality management system planning	4.2.3
5.5 Responsibility, authority and communication [title only]	
5.5.1 Responsibility and authority	4.1.2.1
5.5.2 Management representative	4.1.2.3
5.5.3 Internal communication	
5.6 Management review [title only]	
5.6.1 General	4.1.3
5.6.2 Review input	
5.6.3 Review output	
6 Resource management [title only]	
6.1 Provision of resources	4.1.2.2
6.2 Human resources [title only]	
6.2.1 General	4.1.2.2
6.2.2 Competence, awareness and training	4.18
6.3 Infrastructure	4.9
6.4 Work environment	4.9
7 Product realization [title only]	
7.1 Planning of product realization	4.2.3 + 4.10.1
7.2 Customer-related processes [title only]	
7.2.1 Determination of requirements related to the product	4.3.2 + 4.4.4
7.2.2 Review of requirements related to the product	4.3.2 + 4.3.3 + 4.3.4
7.2.3 Customer communication	4.3.2
7.3 Design and development [title only]	
7.3.1 Design and development planning	4.4.2 + 4.4.3
7.3.2 Design and development inputs	4.4.4

Table B.2 — Correspondence between ISO 9001:2000 and ISO 9001:1994 (*continued*)

ISO 9001:2000	ISO 9001:1994
7.3.3 Design and development outputs	4.4.5
7.3.4 Design and development review	4.4.6
7.3.5 Design and development verification	4.4.7
7.3.6 Design and development validation	4.4.8
7.3.7 Control of design and development changes	4.4.9
7.4 Purchasing [title only]	
7.4.1 Purchasing process	4.6.2
7.4.2 Purchasing information	4.6.3
7.4.3 Verification of purchased product	4.6.4 + 4.10.2
7.5 Production and service provision [title only]	
7.5.1 Control of production and service provision	4.9 + 4.15.6 + 4.19
7.5.2 Validation of processes for production and service provision	4.9
7.5.3 Identification and traceability	4.8 + 4.10.5 + 4.12
7.5.4 Customer property	4.7
7.5.5 Preservation of product	4.15.2 + 4.15.3 + 4.15.4 +.4.15.5
7.6 Control of monitoring and measuring devices	4.11.1 + 4.11.2
8 Measurement, analysis and improvement [title only]	
8.1 General	4.10.1 + 4.20.1 + 4.20.2
8.2 Monitoring and measurement [title only]	
8.2.1 Customer satisfaction	
8.2.2 Internal audit	4.17
8.2.3 Monitoring and measurement of processes	4.17 + 4.20.1 + 4.20.2
8.2.4 Monitoring and measurement of product	4.10.2 + 4.10.3 + 4.10.4 + 4.10.5 + 4.20.1 + 4.20.2
8.3 Control of nonconforming product	4.13.1 + 4.13.2
8.4 Analysis of data	4.20.1 + 4.20.2
8.5 Improvement [title only]	
8.5.1 Continual improvement	4.1.3
8.5.2 Corrective action	4.14.1 + 4.14.2
8.5.3 Preventive action	4.14.1 + 4.14.3

Bibliography

[1] ISO 9000-3:1997, *Quality management and quality assurance standards — Part 3: Guidelines for the application of ISO 9001:1994 to the development, supply, installation and maintenance of computer software*.

[2] ISO 9004:2000, *Quality management systems — Guidelines for performance improvements*.

[3] ISO 10005:1995, *Quality management — Guidelines for quality plans*.

[4] ISO 10006:1997, *Quality management — Guidelines to quality in project management*.

[5] ISO 10007:1995, *Quality management — Guidelines for configuration management*.

[6] ISO 10011-1:1990, *Guidelines for auditing quality systems — Part 1: Auditing*[1)].

[7] ISO 10011-2:1991, *Guidelines for auditing quality systems — Part 2: Qualification criteria for quality systems auditors*[1)].

[8] ISO 10011-3:1991, *Guidelines for auditing quality systems — Part 3: Management of audit programmes*[1)].

[9] ISO 10012-1:1992, *Quality assurance requirements for measuring equipment — Part 1: Metrological confirmation system for measuring equipment*.

[10] ISO 10012-2:1997, *Quality assurance for measuring equipment — Part 2: Guidelines for control of measurement processes*.

[11] ISO 10013:1995, *Guidelines for developing quality manuals*.

[12] ISO/TR 10014:1998, *Guidelines for managing the economics of quality*.

[13] ISO 10015:1999, *Quality management — Guidelines for training*.

[14] ISO/TR 10017:1999, *Guidance on statistical techniques for ISO 9001:1994*.

[15] ISO 14001:1996, *Environmental management systems — Specification with guidance for use*.

[16] IEC 60300-1:—[2)], *Dependability management — Part 1: Dependability programme management*.

[17] *Quality Management Principles Brochure*[3)].

[18] *ISO 9000 + ISO 14000 News* (a bimonthly publication which provides comprehensive coverage of international developments relating to ISO's management system standards, including news of their implementation by diverse organizations around the world)[4)].

[19] Reference websites: http://www.iso.ch
http://www.bsi.org.uk/iso-tc176-sc2

1) To be revised as ISO 19011, *Guidelines on quality and/or environmental management systems auditing*.

2) To be published. (Revision of ISO 9000-4:1993)

3) Available from website: http://www.iso.ch

4) Available from ISO Central Secretariat (sales@iso.ch).

Additional resources on the ANSI/ISO/ASQ Q9000:2000 Standards available from ASQ Quality Press:

ISO 9001:2000 Explained, Second Edition
Charles A. Cianfrani, Joseph J. Tsiakals, and John E. (Jack) West
http://qualitypress.asq.org/perl/catalog.cgi?item=H1104

The ISO Lesson Guide 2000: Pocket Guide to Q9001:2000, Second Edition
Dennis Arter and J. P. Russell
http://qualitypress.asq.org/perl/catalog.cgi?item=H1102

ISO 9001:2000 – An Audio Workshop and Master Slide Presentation
John E. (Jack) West and Charles A. Cianfrani
http://qualitypress.asq.org/perl/catalog.cgi?item=H1106

ISO 9001:2000 Quick Reference
Jeanne Ketola and Kathy Roberts
http://qualitypress.asq.org/perl/catalog.cgi?item=H1107

ISO 9000 at the Front Line
William A. Levinson
http://qualitypress.asq.org/perl/catalog.cgi?item=H0987

After the Quality Audit: Closing the Loop on the Audit Process, Second Edition
J. P. Russell and Terry Regel
http://qualitypress.asq.org/perl/catalog.cgi?item=H1070

Internal Quality Auditing
Denis Pronovost
http://qualitypress.asq.org/perl/catalog.cgi?item=H1069

Quality Press has created an ISO 9000:2000 Resource Materials web page. This convenient online resource contains links to all the books, journals, standards, and courses that are available through ASQ (as well as general information and FAQs) on this important revision to the standards. You can visit this page from our Online Bookstore at http://qualitypress.asq.org.

To request a complimentary catalog of ASQ Quality Press publications, call 800-248-1946, or visit our Online Bookstore at http://qualitypress.asq.org.

American Society for Quality

Quality Press
P.O. Box 3005
Milwaukee, Wisconsin 53201-3005
800-248-1946
Fax 414-272-1734
www.asq.org
http://qualitypress.asq.org
http://standardsgroup.asq.org

T2101E

AMERICAN NATIONAL STANDARD

Quality management systems— Guidelines for performance improvements

Approved as a American National Standard by:
American Society for Quality

An American National Standard Approved on December 13, 2000

Note: As used in this document, the term "International Standard" refers to the American National Standard adoption of this and other International Standards.

ASQ will consider requests for change and information on the submittal of such requests regarding this Standard. All requests should be in writing to the attention of the Standards administrator at the address below.

ASQ Mission: The American Society for Quality advances individual and organizational performance excellence worldwide by providing opportunities for learning, quality improvement, and knowledge exchange.

Published by:

American Society for Quality

ASQ

Quality Press
P.O. Box 3005
Milwaukee, Wisconsin 53201-3005
800-248-1946
Fax 414-272-1734
www.asq.org
http://qualitypress.asq.org
http://standardsgroup.asq.org

Contents

Page

Annexes

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 9004 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 2, *Quality systems*.

This second edition of ISO 9004 cancels and replaces ISO 9004-1:1994, which has been technically revised. The title has been modified to reflect the comprehensiveness of the quality management system. Many of the existing International Standards within the ISO 9000 family will be reviewed for withdrawal, or for re-issue as Technical Reports, as many of their provisions are incorporated into this International Standard.

In comparison to previous editions, ISO 9001 and ISO 9004 now form a consistent pair of standards on quality management. ISO 9001 aims to give quality assurance of product and to enhance customer satisfaction, while ISO 9004 uses a broader perspective of quality management to give guidance for performance improvement.

Annexes A and B of this International Standard are for information only.

Introduction

0.1 General

The adoption of a quality management system should be a strategic decision by the top management of an organization. The design and implementation of an organization's quality management system is influenced by varying needs, particular objectives, the products provided, the processes employed and the size and structure of the organization. This International Standard is based on eight quality management principles. However, it is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

The purpose of an organization is

— to identify and meet the needs and expectations of its customers and other interested parties (people in the organization, suppliers, owners, society), to achieve competitive advantage, and to do this in an effective and efficient manner, and

— to achieve, maintain, and improve overall organizational performance and capabilities.

The application of quality management principles not only provides direct benefits but also makes an important contribution to managing costs and risks. Benefit, cost and risk management considerations are important for the organization, its customers and other interested parties. These considerations on overall performance of the organization may impact

— customer loyalty,

— repeat business and referral,

— operational results such as revenue and market share,

— flexible and fast responses to market opportunities,

— costs and cycle times through effective and efficient use of resources,

— alignment of processes which will best achieve desired results,

— competitive advantage through improved organizational capabilities,

— understanding and motivation of people towards the organization's goals and objectives, as well as participation in continual improvement,

— confidence of interested parties in the effectiveness and efficiency of the organization, as demonstrated by the financial and social benefits from the organization's performance, product life cycle, and reputation,

— ability to create value for both the organization and its suppliers by optimization of costs and resources as well as flexibility and speed of joint responses to changing markets.

0.2 Process approach

This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness and efficiency of a quality management system to enhance interested party satisfaction by meeting interested party requirements.

For an organization to function effectively and efficiently, it has to identify and manage numerous linked activities. An activity using resources, and managed in order to enable the transformation of inputs into outputs, is considered as a process. Often the output from one process directly forms the input to the next.

The application of a system of processes within an organization, together with the identification and interactions and managing of these processes can be referred to as the “process approach”.

An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as their combination and interaction.

When used within a quality management system, such an approach emphasizes the importance of

a) understanding and fulfilling the requirements,

b) the need to consider processes in terms of added value,

c) obtaining results of process performance and effectiveness, and

d) continual improvement of processes based on objective measurement.

The model of a process-based quality management system shown in Figure 1 illustrates the process linkages presented in clauses 4 to 8. This illustration shows that interested parties play a significant role in defining requirements as inputs. Monitoring the satisfaction of interested parties requires the evaluation of information relating to the perception of interested parties as to whether the organization has met their requirements. The model shown in Figure 1 does not show processes at a detailed level.

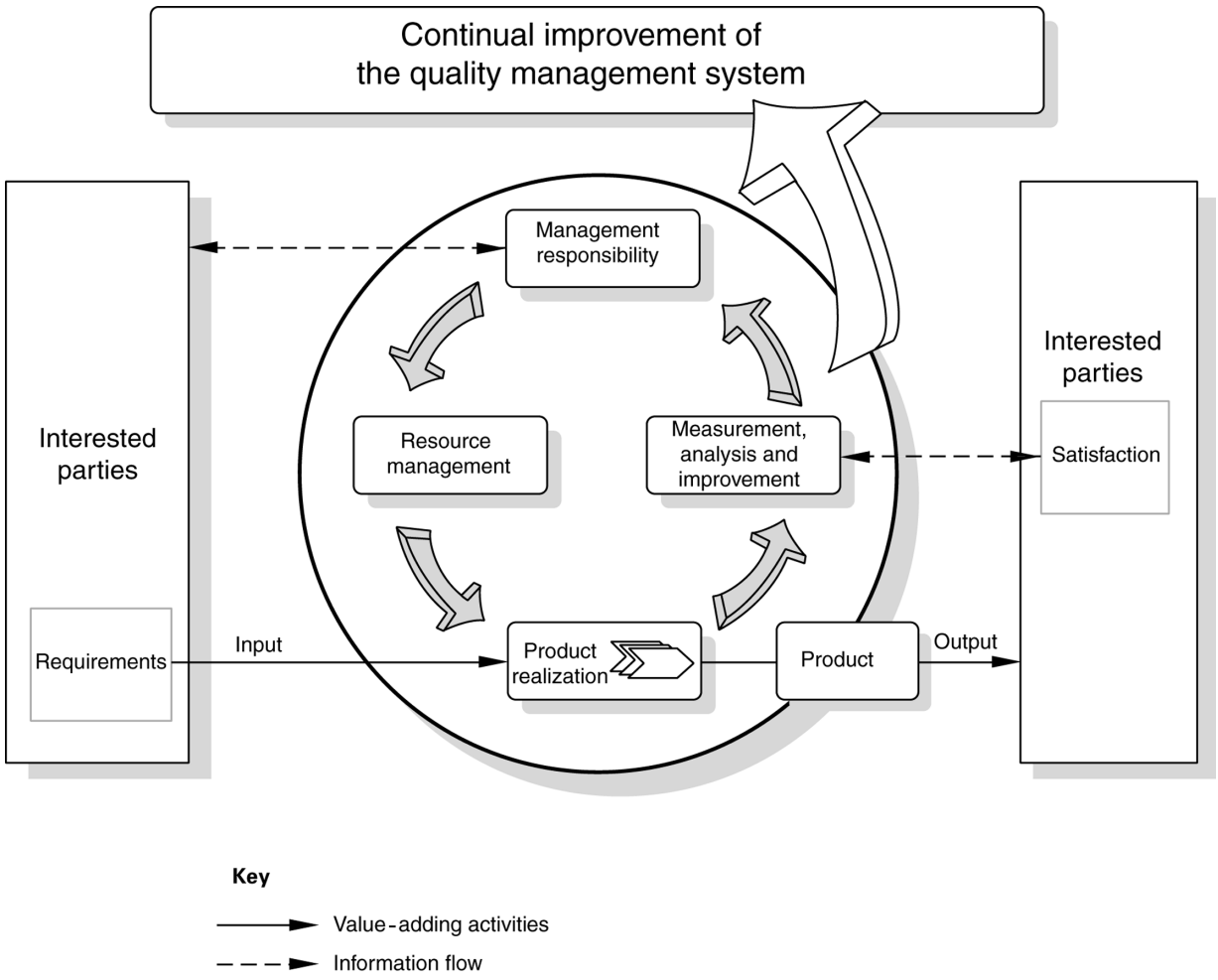


Figure 1 — Model of a process-based quality management system

0.3 Relationship with ISO 9001

The present editions of ISO 9001 and ISO 9004 have been developed as a consistent pair of quality management system standards which have been designed to complement each other but can also be used independently. Although the two International Standards have different scopes, they have similar structures in order to assist their application as a consistent pair.

ISO 9001 specifies requirements for a quality management system that can be used for internal application by organizations, or for certification, or for contractual purposes. It focuses on the effectiveness of the quality management system in meeting customer requirements.

ISO 9004 gives guidance on a wider range of objectives of a quality management system than does ISO 9001, particularly for the continual improvement of an organization's overall performance and efficiency, as well as its effectiveness. ISO 9004 is recommended as a guide for organizations whose top management wishes to move beyond the requirements of ISO 9001, in pursuit of continual improvement of performance. However, it is not intended for certification or for contractual purposes.

For further benefit to the user, the basic content of the ISO 9001 requirements are included in boxed text following the comparable clause in this International Standard. Information marked “NOTE” is for guidance in understanding or clarification.

0.4 Compatibility with other management systems

This International Standard does not include guidance specific to other management systems, such as those particular to environmental management, occupational health and safety management, financial management, or risk management. However, this International Standard enables an organization to align or integrate its own quality management system with related management systems. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that follows the guidelines of this International Standard.

Quality management systems — Guidelines for performance improvements

1 Scope

This International Standard provides guidelines beyond the requirements given in ISO 9001 in order to consider both the effectiveness and efficiency of a quality management system, and consequently the potential for improvement of the performance of an organization. When compared to ISO 9001, the objectives of customer satisfaction and product quality are extended to include the satisfaction of interested parties and the performance of the organization.

This International Standard is applicable to the processes of the organization and consequently the quality management principles on which it is based can be deployed throughout the organization. The focus of this International Standard is the achievement of ongoing improvement, measured through the satisfaction of customers and other interested parties.

This International Standard consists of guidance and recommendations and is not intended for certification, regulatory or contractual use, nor as a guide to the implementation of ISO 9001.

2 Normative reference

The following normative document contains provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 9000:2000, *Quality management systems — Fundamentals and vocabulary*.

3 Terms and definitions

For the purposes of this International Standard, the terms and definitions given in ISO 9000 apply.

The following terms, used in this edition of ISO 9004 to describe the supply-chain, have been changed to reflect the vocabulary currently used:

supplier → **organization** → **customer (interested parties)**

Throughout the text of this International Standard, wherever the term “product” occurs, it can also mean “service”.

4 Quality management system

4.1 Managing systems and processes

Leading and operating an organization successfully requires managing it in a systematic and visible manner. Success should result from implementing and maintaining a management system that is designed to continually improve the effectiveness and efficiency of the organization's performance by considering the needs of interested parties. Managing an organization includes quality management, among other management disciplines.

Top management should establish a customer-oriented organization

a) by defining systems and processes that can be clearly understood, managed and improved in effectiveness as well as efficiency, and

b) by ensuring effective and efficient operation and control of processes and the measures and data used to determine satisfactory performance of the organization.

Examples of activities to establish a customer-oriented organization include

— defining and promoting processes that lead to improved organizational performance,

— acquiring and using process data and information on a continuing basis,

— directing progress towards continual improvement, and

— using suitable methods to evaluate process improvement, such as self-assessments and management review.

Examples of self-assessment and continual improvement processes are given in annexes A and B respectively.

ISO 9001:2000, Quality management systems — Requirements

4 Quality management system

4.1 General requirements

The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.

The organization shall

a) identify the processes needed for the quality management system and their application throughout the organization,

b) determine the sequence and interaction of these processes,

c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,

d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,

e) monitor, measure and analyse these processes, and

f) implement actions necessary to achieve planned results and continual improvement of these processes.

These processes shall be managed by the organization in accordance with the requirements of this International Standard.

Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system.

NOTE Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement.

4.2 Documentation

Management should define the documentation, including the relevant records, needed to establish, implement and maintain the quality management system and to support an effective and efficient operation of the organization's processes.

The nature and extent of the documentation should satisfy the contractual, statutory and regulatory requirements, and the needs and expectations of customers and other interested parties and should be appropriate to the organization. Documentation may be in any form or medium suitable for the needs of the organization.

In order to provide documentation to satisfy the needs and expectations of interested parties management should consider

— contractual requirements from the customer and other interested parties,

— acceptance of international, national, regional and industry sector standards,

— relevant statutory and regulatory requirements,

— decisions by the organization,

— sources of external information relevant for the development of the organization's competencies, and

— information about the needs and expectations of interested parties.

The generation, use and control of documentation should be evaluated with respect to the effectiveness and efficiency of the organization against criteria such as

— functionality (such as speed of processing),

— user friendliness,

— resources needed,

— policies and objectives,

— current and future requirements related to managing knowledge,

— benchmarking of documentation systems, and

— interfaces used by organization's customers, suppliers and other interested parties.

Access to documentation should be ensured for people in the organization and to other interested parties, based on the organization's communication policy.

ISO 9001:2000, Quality management systems — Requirements

4.2 Documentation requirements

4.2.1 General

The quality management system documentation shall include

a) documented statements of a quality policy and quality objectives,

b) a quality manual,

c) documented procedures required by this International Standard,

d) documents needed by the organization to ensure the effective planning, operation and control of its processes, and

e) records required by this International Standard.

NOTE 1 Where the term “documented procedure” appears within this International Standard, this means that the procedure is established, documented, implemented and maintained.

NOTE 2 The extent of the quality management system documentation can differ from one organization to another due to

a) the size of organization and type of activities,

b) the complexity of processes and their interactions, and

c) the competence of personnel.

NOTE 3 The documentation can be in any form or type of medium.

4.2.2 Quality manual

The organization shall establish and maintain a quality manual that includes

a) the scope of the quality management system, including details of and justification for any exclusions,

b) the documented procedures established for the quality management system, or reference to them, and

c) a description of the interaction between the processes of the quality management system.

4.2.3 Control of documents

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

A documented procedure shall be established to define the controls needed

a) to approve documents for adequacy prior to issue,

b) to review and update as necessary and re-approve documents,

c) to ensure that changes and the current revision status of documents are identified,

d) to ensure that relevant versions of applicable documents are available at points of use,

e) to ensure that documents remain legible and readily identifiable,

f) to ensure that documents of external origin are identified and their distribution controlled, and

g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

4.2.4 Control of records

Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

4.3 Use of quality management principles

To lead and operate an organization successfully, it is necessary to manage it in a systematic and visible manner. The guidance to management offered in this International Standard is based on eight quality management principles.

These principles have been developed for use by top management in order to lead the organization toward improved performance. These quality management principles are integrated in the contents of this International Standard and are listed below

a) **Customer focus**

Organizations depend on their customers and therefore should understand current and future customer needs, should meet customer requirements and strive to exceed customer expectations.

b) **Leadership**

Leaders establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization's objectives.

c) **Involvement of people**

People at all levels are the essence of an organization and their full involvement enables their abilities to be used for the organization's benefit.

d) **Process approach**

A desired result is achieved more efficiently when activities and related resources are managed as a process.

e) **System approach to management**

Identifying, understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its objectives.

f) **Continual improvement**

Continual improvement of the organization's overall performance should be a permanent objective of the organization.

g) **Factual approach to decision making**

Effective decisions are based on the analysis of data and information.

h) **Mutually beneficial supplier relationships**

An organization and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value.

Successful use of the eight management principles by an organization will result in benefits to interested parties, such as improved monetary returns, the creation of value and increased stability.

5 Management responsibility

5.1 General guidance

5.1.1 Introduction

Leadership, commitment and the active involvement of the top management are essential for developing and maintaining an effective and efficient quality management system to achieve benefits for interested parties. To achieve these benefits, it is necessary to establish, sustain and increase customer satisfaction. Top management should consider actions such as

— establishing a vision, policies and strategic objectives consistent with the purpose of the organization,

— leading the organization by example, in order to develop trust within its people,

— communicating organizational direction and values regarding quality and the quality management system,

— participating in improvement projects, searching for new methods, solutions and products,

— obtaining feedback directly on the effectiveness and efficiency of the quality management system,

— identifying the product realization processes that provide added value to the organization,

— identifying the support processes that influence the effectiveness and efficiency of the realization processes,

— creating an environment that encourages the involvement and development of people, and

— provision of the structure and resources that are necessary to support the organization's strategic plans.

Top management should also define methods for measurement of the organization's performance in order to determine whether planned objectives have been achieved.

Methods include

— financial measurement,

— measurement of process performance throughout the organization,

— external measurement, such as benchmarking and third-party evaluation,

— assessment of the satisfaction of customers, people in the organization and other interested parties,

— assessment of the perceptions of customers and other interested parties of performance of products provided, and

— measurement of other success factors identified by management.

Information derived from such measurements and assessments should also be considered as input to management review in order to ensure that continual improvement of the quality management system is the driver for performance improvement of the organization.

5.1.2 Issues to be considered

When developing, implementing and managing the organization's quality management system, management should consider the quality management principles outlined in 4.3.

On the basis of these principles, top management should demonstrate leadership in, and commitment to, the following activities:

— understanding current and future customer needs and expectations, in addition to requirements;

— promoting policies and objectives to increase awareness, motivation and involvement of people in the organization;

— establishing continual improvement as an objective for processes of the organization;

— planning for the future of the organization and managing change;

— setting and communicating a framework for achieving the satisfaction of interested parties.

In addition to small-step or ongoing continual improvement, top management should also consider breakthrough changes to processes as a way to improve the organization's performance. During such changes, management should take steps to ensure that the resources and communication needed to maintain the functions of the quality management system are provided.

Top management should identify the organization's product realization processes, as these are directly related to the success of the organization. Top management should also identify those support processes that affect either the effectiveness and efficiency of the realization processes or the needs and expectations of interested parties.

Management should ensure that processes operate as an effective and efficient network. Management should analyse and optimize the interaction of processes, including both realization processes and support processes.

Consideration should be given to

— ensuring that the sequence and interaction of processes are designed to achieve the desired results effectively and efficiently,

— ensuring process inputs, activities and outputs are clearly defined and controlled,

— monitoring inputs and outputs to verify that individual processes are linked and operate effectively and efficiently,

— identifying and managing risks, and exploiting performance improvement opportunities,

— conducting data analysis to facilitate continual improvement of processes,

— identifying process owners and giving them full responsibility and authority,

— managing each process to achieve the process objectives, and

— the needs and expectations of interested parties.

ISO 9001:2000, Quality management systems — Requirements

5 Management responsibility

5.1 Management commitment

Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by

a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,

b) establishing the quality policy,

c) ensuring that quality objectives are established,

d) conducting management reviews, and

e) ensuring the availability of resources.

5.2 Needs and expectations of interested parties

5.2.1 General

Every organization has interested parties, each party having needs and expectations. Interested parties of organizations include

— customers and end-users,

— people in the organization,

— owners/investors (such as shareholders, individuals or groups, including the public sector, that have a specific interest in the organization),

— suppliers and partners, and

— society in terms of the community and the public affected by the organization or its products.

5.2.2 Needs and expectations

The success of the organization depends on understanding and satisfying the current and future needs and expectations of present and potential customers and end-users, as well as understanding and considering those of other interested parties.

In order to understand and meet the needs and expectations of interested parties, an organization should

— identify its interested parties and maintain a balanced response to their needs and expectations,

— translate identified needs and expectations into requirements,

— communicate the requirements throughout the organization, and

— focus on process improvement to ensure value for the identified interested parties.

To satisfy customer and end-user needs and expectations, the management of an organization should

— understand the needs and expectations of its customers, including those of potential customers,

— determine key product characteristics for its customers and end-users,

— identify and assess competition in its market, and

— identify market opportunities, weaknesses and future competitive advantage.

Examples of customer and end-user needs and expectations, as related to the organization's products, include

— conformity,

— dependability,

— availability,

— delivery,

— post-realization activities,

— price and life-cycle costs,

— product safety,

— product liability, and

— environmental impact.

The organization should identify its people's needs and expectations for recognition, work satisfaction, and personal development. Such attention helps to ensure that the involvement and motivation of people are as strong as possible.

The organization should define financial and other results that satisfy the identified needs and expectations of owners and investors.

Management should consider the potential benefits of establishing partnerships with suppliers to the organization, in order to create value for both parties. A partnership should be based on a joint strategy, sharing knowledge as well as gains and losses. When establishing partnerships, an organization should

— identify key suppliers, and other organizations, as potential partners,

— jointly establish a clear understanding of customers' needs and expectations,

— jointly establish a clear understanding of the partners' needs and expectations, and

— set goals to secure opportunities for continuing partnerships.

In considering its relationships with society, the organization should

— demonstrate responsibility for health and safety,

— consider environmental impact, including conservation of energy and natural resources,

— identify applicable statutory and regulatory requirements, and

— identify the current and potential impacts on society in general, and the local community in particular, of its products, processes and activities.

ISO 9001:2000, Quality management systems — Requirements

5.2 Customer focus

Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction.

5.2.3 Statutory and regulatory requirements

Management should ensure that the organization has knowledge of the statutory and regulatory requirements that apply to its products, processes and activities and should include such requirements as part of the quality management system. Consideration should also be given to

— the promotion of ethical, effective and efficient compliance with current and prospective requirements,

— the benefits to interested parties from exceeding compliance, and

— the role of the organization in the protection of community interests.

5.3 Quality policy

Top management should use the quality policy as a means of leading the organization toward improvement of its performance.

An organization's quality policy should be an equal and consistent part of the organization's overall policies and strategy.

In establishing the quality policy, top management should consider

— the level and type of future improvement needed for the organization to be successful,

— the expected or desired degree of customer satisfaction,

— the development of people in the organization,

— the needs and expectations of other interested parties,

— the resources needed to go beyond ISO 9001 requirements, and

— the potential contributions of suppliers and partners.

The quality policy can be used for improvement provided that

— it is consistent with top management's vision and strategy for the organization's future,

— it permits quality objectives to be understood and pursued throughout the organization,

— it demonstrates top management's commitment to quality and the provision of adequate resources for achievement of objectives,

— it aids in promoting a commitment to quality throughout the organization, with clear leadership by top management,

— it includes continual improvement as related to satisfaction of the needs and expectations of customers and other interested parties, and

— it is effectively formulated and efficiently communicated.

As with other business policies, the quality policy should be periodically reviewed.

ISO 9001:2000, Quality management systems — Requirements

5.3 Quality policy

Top management shall ensure that the quality policy

a) is appropriate to the purpose of the organization,

b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system,

c) provides a framework for establishing and reviewing quality objectives,

d) is communicated and understood within the organization, and

e) is reviewed for continuing suitability.

5.4 Planning

5.4.1 Quality objectives

The organization's strategic planning and the quality policy provide a framework for the setting of quality objectives. Top management should establish these objectives, leading to improvement of the organization's performance. The objectives should be capable of being measured in order to facilitate an effective and efficient review by management. When establishing these objectives, management should also consider

— current and future needs of the organization and the markets served,

— relevant findings from management reviews,

— current product and process performance,

— levels of satisfaction of interested parties,

— self-assessment results,

— benchmarking, competitor analysis, opportunities for improvement, and

— resources needed to meet the objectives.

The quality objectives should be communicated in such a way that people in the organization can contribute to their achievement. Responsibility for deployment of quality objectives should be defined. Objectives should be systematically reviewed and revised as necessary.

ISO 9001:2000, Quality management systems — Requirements

5.4 Planning

5.4.1 Quality objectives

Top management shall ensure that quality objectives, including those needed to meet requirements for product, are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

5.4.2 Quality planning

Management should take responsibility for the quality planning of the organization. This planning should focus on defining the processes needed to meet effectively and efficiently the organization's quality objectives and requirements consistent with the strategy of the organization.

Inputs for effective and efficient planning include

— strategies of the organization,

— defined organizational objectives,

— defined needs and expectations of the customers and other interested parties,

— evaluation of statutory and regulatory requirements,

— evaluation of performance data of the products,

— evaluation of performance data of processes,

— lessons learned from previous experience,

— indicated opportunities for improvement, and

— related risk assessment and mitigation data.

Outputs of quality planning for the organization should define the product realization and support processes needed in terms such as

— skills and knowledge needed by the organization,

— responsibility and authority for implementation of process improvement plans,

— resources needed, such as financial and infrastructure,

— metrics for evaluating the achievement of the organization's performance improvement

— needs for improvement including methods and tools, and

— needs for documentation, including records.

Management should systematically review the outputs to ensure the effectiveness and efficiency of the processes of the organization.

ISO 9001:2000, Quality management systems — Requirements

5.4.2 Quality management system planning

Top management shall ensure that

a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and

b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

Top management should define and then communicate the responsibility and authority in order to implement and maintain an effective and efficient quality management system.

People throughout the organization should be given responsibilities and authority to enable them to contribute to the achievement of the quality objectives and to establish their involvement, motivation and commitment.

ISO 9001:2000, Quality management systems — Requirements

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

Top management shall ensure that responsibilities and authorities are defined and communicated within the organization.

5.5.2 Management representative

A management representative should be appointed and given authority by top management to manage, monitor, evaluate and coordinate the quality management system. This appointment is to enhance effective and efficient operation and improvement of the quality management system. The representative should report to top management and communicate with customers and other interested parties on matters pertaining to the quality management system.

ISO 9001:2000, Quality management systems — Requirements

5.5.2 Management representative

Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes

a) ensuring that processes needed for the quality management system are established, implemented and maintained,

b) reporting to top management on the performance of the quality management system and any need for improvement, and

c) ensuring the promotion of awareness of customer requirements throughout the organization.

NOTE The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.

5.5.3 Internal communication

The management of the organization should define and implement an effective and efficient process for communicating the quality policy, requirements, objectives and accomplishments. Providing such information can aid in the organization's performance improvement and directly involves its people in the achievement of quality objectives. Management should actively encourage feedback and communication from people in the organization as a means of involving them.

Activities for communicating include, for example

— management-led communication in work areas,

— team briefings and other meetings, such as for recognition of achievement,

— notice-boards, in-house journals/magazines,

— audio-visual and electronic media, such as email and websites, and

— employee surveys and suggestion schemes.

ISO 9001:2000, Quality management systems — Requirements

5.5.3 Internal communication

Top management shall ensure that appropriate communication channels are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

5.6 Management review

5.6.1 General

Top management should develop the management review activity beyond verification of the effectiveness and efficiency of the quality management system into a process that extends to the whole organization, and which also evaluates the efficiency of the system. Management reviews should be platforms for the exchange of new ideas, with open discussion and evaluation of the inputs being stimulated by the leadership of top management.

To add value to the organization from management review, top management should control the performance of realization and support processes by systematic review based on the quality management principles. The frequency of review should be determined by the needs of the organization. Inputs to the review process should result in outputs that extend beyond the effectiveness and efficiency of the quality management system. Outputs from reviews should provide data for use in planning for performance improvement of the organization.

ISO 9001:2000, Quality management systems — Requirements

5.6 Management review

5.6.1 General

Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews shall be maintained.

5.6.2 Review input

Inputs to evaluate efficiency as well as effectiveness of the quality management system should consider the customer and other interested parties and should include

— status and results of quality objectives and improvement activities,

— status of management review action items,

— results of audits and self-assessment of the organization,

— feedback on the satisfaction of interested parties, perhaps even to the point of their participation,

— market-related factors such as technology, research and development, and competitor performance,

— results from benchmarking activities,

— performance of suppliers,

— new opportunities for improvement,

— control of process and product nonconformities,

— marketplace evaluation and strategies,

— status of strategic partnership activities,

— financial effects of quality related activities, and

— other factors which may impact the organization, such as financial, social or environmental conditions, and relevant statutory and regulatory changes.

ISO 9001:2000, Quality management systems — Requirements

5.6.2 Review input

The input to management review shall include information on

a) results of audits,

b) customer feedback,

c) process performance and product conformity,

d) status of preventive and corrective actions,

e) follow-up actions from previous management reviews,

f) changes that could affect the quality management system, and

g) recommendations for improvement.

5.6.3 Review output

By extending management review beyond verification of the quality management system, the outputs of management review can be used by top management as inputs to improvement processes. Top management can use this review process as a powerful tool in the identification of opportunities for performance improvement of the organization. The schedule of reviews should facilitate the timely provision of data in the context of strategic planning for the organization. Selected output should be communicated to demonstrate to the people in the organization how the management review process leads to new objectives that will benefit the organization.

Additional outputs to enhance efficiency include, for example

— performance objectives for products and processes,

— performance improvement objectives for the organization,

— appraisal of the suitability of the organization's structure and resources,

— strategies and initiatives for marketing, products, and satisfaction of customers and other interested parties,

— loss prevention and mitigation plans for identified risks, and

— information for strategic planning for future needs of the organization.

Records should be sufficient to provide for traceability and to facilitate evaluation of the management review process itself, in order to ensure its continued effectiveness and added value to the organization.

ISO 9001:2000, Quality management systems — Requirements

5.6.3 Review output

The output from the management review shall include any decisions and actions related to

a) improvement of the effectiveness of the quality management system and its processes,

b) improvement of product related to customer requirements, and

c) resource needs.

6 Resource management

6.1 General guidance

6.1.1 Introduction

Top management should ensure that the resources essential to the implementation of strategy and the achievement of the organization's objectives are identified and made available. This should include resources for operation and improvement of the quality management system, and the satisfaction of customers and other interested parties. Resources may be people, infrastructure, work environment, information, suppliers and partners, natural resources and financial resources.

6.1.2 Issues to be considered

Consideration should be given to resources to improve the performance of the organization, such as

— effective, efficient and timely provision of resources in relation to opportunities and constraints,

— tangible resources such as improved realization and support facilities,

— intangible resources such as intellectual property,

— resources and mechanisms to encourage innovative continual improvement,

— organization structures, including project and matrix management needs,

— information management and technology,

— enhancement of competence via focused training, education and learning,

— development of leadership skills and profiles for the future managers of the organization,

— use of natural resources and the impact of resources on the environment, and

— planning for future resource needs.

ISO 9001:2000, Quality management systems — Requirements

6 Resource management

6.1 Provision of resources

The organization shall determine and provide the resources needed

a) to implement and maintain the quality management system and continually improve its effectiveness, and

b) to enhance customer satisfaction by meeting customer requirements.

6.2 People

6.2.1 Involvement of people

Management should improve both the effectiveness and efficiency of the organization, including the quality management system, through the involvement and support of people. As an aid to achieving its performance improvement objectives, the organization should encourage the involvement and development of its people

— by providing ongoing training and career planning,

— by defining their responsibilities and authorities,

— by establishing individual and team objectives, managing process performance and evaluating results,

— by facilitating involvement in objective setting and decision making,

— by recognizing and rewarding,

— by facilitating the open, two-way communication of information,

— by continually reviewing the needs of its people,

— by creating conditions to encourage innovation,

— by ensuring effective teamwork,

— by communicating suggestions and opinions,

— by using measurements of its people's satisfaction, and

— by investigating the reasons why people join and leave the organization.

ISO 9001:2000, Quality management systems — Requirements

6.2 Human resources

6.2.1 General

Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.

6.2.2 Competence, awareness and training

6.2.2.1 Competence

Management should ensure that the necessary competence is available for the effective and efficient operation of the organization. Management should consider analysis of both the present and expected competence needs as compared to the competence already existing in the organization.

Consideration of the need for competence includes sources such as

— future demands related to strategic and operational plans and objectives,

— anticipated management and workforce succession needs,

— changes to the organization's processes, tools and equipment,

— evaluation of the competence of individual people to perform defined activities, and

— statutory and regulatory requirements, and standards, affecting the organization and its interested parties.

6.2.2.2 Awareness and training

Planning for education and training needs should take account of change caused by the nature of the organization's processes, the stages of development of people and the culture of the organization.

The objective is to provide people with knowledge and skills which, together with experience, improve their competence.

Education and training should emphasize the importance of meeting requirements and the needs and expectations of the customer and other interested parties. It should also include awareness of the consequences to the organization and its people of failing to meet the requirements.

To support the achievement of the organization's objectives and the development of its people, planning for education and training should consider

— experience of people,

— tacit and explicit knowledge,

— leadership and management skills,

— planning and improvement tools,

— teambuilding,

— problem solving,

— communication skills,

— culture and social behaviour,

— knowledge of markets and the needs and expectations of customers and other interested parties, and

— creativity and innovation.

To facilitate the involvement of people, education and training also include

— the vision for the future of the organization,

— the organization's policies and objectives,

— organizational change and development,

— the initiation and implementation of improvement processes,

— benefits from creativity and innovation,

— the organization's impact on society,

— introductory programmes for new people, and

— periodic refresher programmes for people already trained.

Training plans should include

— objectives,

— programmes and methods,

— resources needed,

— identification of necessary internal support,

— evaluation in terms of enhanced competence of people, and

— measurement of the effectiveness and the impact on the organization.

The education and training provided should be evaluated in terms of expectations and impact on the effectiveness and efficiency of the organization as a means of improving future training plans.

ISO 9001:2000, Quality management systems — Requirements

6.2.2 Competence, awareness and training

The organization shall

a) determine the necessary competence for personnel performing work affecting product quality,

b) provide training or take other actions to satisfy these needs,

c) evaluate the effectiveness of the actions taken,

d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and

e) maintain appropriate records of education, training, skills and experience.

6.3 Infrastructure

Management should define the infrastructure necessary for the realization of products while considering the needs and expectations of interested parties. The infrastructure includes resources such as plant, workspace, tools and equipment, support services, information and communication technology, and transport facilities.

The process to define the infrastructure necessary for achieving effective and efficient product realization should include the following:

a) provision of an infrastructure, defined in terms such as objectives, function, performance, availability, cost, safety, security and renewal;

b) development and implementation of maintenance methods to ensure that the infrastructure continues to meet the organization's needs; these methods should consider the type and frequency of maintenance and verification of operation of each infrastructure element, based on its criticality and usage;

c) evaluation of the infrastructure against the needs and expectations of interested parties;

d) consideration of environmental issues associated with infrastructure, such as conservation, pollution, waste and recycling.

Natural phenomena that cannot be controlled can impact the infrastructure. The plan for the infrastructure should consider the identification and mitigation of associated risks and should include strategies to protect the interests of interested parties.

ISO 9001:2000, Quality management systems — Requirements

6.3 Infrastructure

The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable

a) buildings, workspace and associated utilities,

b) process equipment (both hardware and software), and

c) supporting services (such as transport or communication).

6.4 Work environment

Management should ensure that the work environment has a positive influence on motivation, satisfaction and performance of people in order to enhance the performance of the organization. Creation of a suitable work environment, as a combination of human and physical factors, should include consideration of

— creative work methods and opportunities for greater involvement to realize the potential of people in the organization,

— safety rules and guidance, including the use of protective equipment,

— ergonomics,

— workplace location,

— social interaction,

— facilities for people in the organization,

— heat, humidity, light, airflow, and

— hygiene, cleanliness, noise, vibration and pollution.

ISO 9001:2000, Quality management systems — Requirements

6.4 Work environment

The organization shall determine and manage the work environment needed to achieve conformity to product requirements.

6.5 Information

Management should treat data as a fundamental resource for conversion to information and the continual development of an organization's knowledge, which is essential for making factual decisions and can stimulate innovation. In order to manage information, the organization should

— identify its information needs,

— identify and access internal and external sources of information,

— convert information to knowledge of use to the organization,

— use the data, information and knowledge to set and meet its strategies and objectives,

— ensure appropriate security and confidentiality, and

— evaluate the benefits derived from use of the information in order to improve managing information and knowledge.

6.6 Suppliers and partnerships

Management should establish relationships with suppliers and partners to promote and facilitate communication with the aim of mutually improving the effectiveness and efficiency of processes that create value. There are various opportunities for organizations to increase value through working with their suppliers and partners, such as

— optimizing the number of suppliers and partners,

— establishing two-way communication at appropriate levels in both organizations to facilitate the rapid solution of problems, and to avoid costly delays or disputes,

— cooperating with suppliers in validation of the capability of their processes,

— monitoring the ability of suppliers to deliver conforming products with the aim of eliminating redundant verifications,

— encouraging suppliers to implement programmes for continual improvement of performance and to participate in other joint improvement initiatives,

— involving suppliers in the organization's design and development activities to share knowledge and effectively and efficiently improve the realization and delivery processes for conforming products,

— involving partners in identification of purchasing needs and joint strategy development, and

— evaluating, recognizing and rewarding efforts and achievements by suppliers and partners.

6.7 Natural resources

Consideration should be given to the availability of natural resources that can influence the performance of the organization. While such resources are often out of the direct control of the organization, they can have significant positive or negative effects on its results. The organization should have plans, or contingency plans, to ensure the availability or replacement of these resources in order to prevent or minimize negative effects on the performance of the organization.

6.8 Financial resources

Resource management should include activities for determining the needs for, and sources of, financial resources. The control of financial resources should include activities for comparing actual usage against plans, and taking necessary action.

Management should plan, make available and control the financial resources necessary to implement and maintain an effective and efficient quality management system and to achieve the organization's objectives. Management should also consider the development of innovative financial methods to support and encourage improvement of the organization's performance.

Improving the effectiveness and efficiency of the quality management system can influence positively the financial results of the organization, for example

a) internally, by reducing process and product failures, or waste in material and time, or

b) externally, by reducing product failures, costs of compensation under guarantees and warranties, and costs of lost customers and markets.

Reporting of such matters can also provide a means of determining ineffective or inefficient activities, and initiating suitable improvement actions.

The financial reporting of activities related to the performance of the quality management system and product conformity should be used in management reviews.

7 Product realization

7.1 General guidance

7.1.1 Introduction

Top management should ensure the effective and efficient operation of realization and support processes and the associated process network so that the organization has the capability of satisfying its interested parties. While realization processes result in products that add value to the organization, support processes are also necessary to the organization and add value indirectly.

Any process is a sequence of related activities or an activity that has both input and output. Management should define the required outputs of processes, and should identify the necessary inputs and activities required for their effective and efficient achievement.

The interrelation of processes can be complex, resulting in process networks. To ensure the effective and efficient operation of the organization, management should recognize that the output of one process may become the input to one or more other processes.

7.1.2 Issues to be considered

Understanding that a process can be represented as a sequence of activities aids management in defining the process inputs. Once the inputs have been defined, the necessary activities, actions and resources required for the process can be determined, in order to achieve the desired outputs.

Results from verification and validation of processes and outputs should also be considered as inputs to a process, to achieve continual improvement of performance and the promotion of excellence throughout the organization. Continual improvement of the organization's processes will improve the effectiveness and efficiency of the quality management system and the organization's performance. Annex B describes a “Process for continual improvement” that can be used to assist in the identification of actions needed for continual improvement of the effectiveness and efficiency of processes.

Processes should be documented to the extent necessary to support effective and efficient operation. Documentation related to processes should support

— identifying and communicating the significant features of the processes,

— training in the operation of processes,

— sharing knowledge and experience in teams and work groups,

— measurement and audit of processes, and

— analysis, review and improvement of processes.

The role of people within the processes should be evaluated in order

— to ensure the health and safety of people,

— to ensure that the necessary skills exist,

— to support coordination of processes,

— to provide for input from people in process analysis, and

— to promote innovation from people.

The drive for continual improvement of the organization's performance should focus on the improvement of the effectiveness and efficiency of processes as the means by which beneficial results are achieved. Increased benefits, improved customer satisfaction, improved use of resources and reduction of waste are examples of measurable results achieved by greater effectiveness and efficiency of processes.

7.1.3 Managing processes

7.1.3.1 General

Management should identify processes needed to realize products to satisfy the requirements of customers and other interested parties. To ensure product realization, consideration should be given to associated support processes as well as desired outputs, process steps, activities, flows, control measures, training needs, equipment, methods, information, materials and other resources.

An operating plan should be defined to manage the processes, including

— input and output requirements (for example specifications and resources),

— activities within the processes,

— verification and validation of processes and products,

— analysis of the process including dependability,

— identification, assessment and mitigation of risk,

— corrective and preventive actions,

— opportunities and actions for process improvement, and

— control of changes to processes and products.

Examples of support processes include

— managing information,

— training of people,

— finance-related activities,

— infrastructure and service maintenance,

— application of industrial safety/protective equipment, and

— marketing.

7.1.3.2 Process inputs, outputs and review

The process approach ensures that process inputs are defined and recorded in order to provide a basis for formulation of requirements to be used for verification and validation of outputs. Inputs can be internal or external to the organization.

Resolution of ambiguous or conflicting input requirements can involve consultation with the affected internal and external parties. Input derived from activities not yet fully evaluated should be subject to evaluation through subsequent review, verification and validation. The organization should identify significant or critical features of products and processes in order to develop an effective and efficient plan for controlling and monitoring the activities within its processes.

Examples of input issues to consider include

— competence of people,

— documentation,

— equipment capability and monitoring, and

— health, safety and work environment.

Process outputs that have been verified against process input requirements, including acceptance criteria, should consider the needs and expectations of customers and other interested parties. For verification purposes, the outputs should be recorded and evaluated against input requirements and acceptance criteria. This evaluation

should identify necessary corrective actions, preventive actions or potential improvements in the effectiveness and efficiency of the process. Verification of the product can be carried out in the process in order to identify variation.

The management of the organization should undertake periodic review of process performance to ensure the process is consistent with the operating plan. Examples of topics for this review include

— reliability and repeatability of the process,

— identification and prevention of potential nonconformities,

— adequacy of design and development inputs and outputs,

— consistency of inputs and outputs with planned objectives,

— potential for improvements, and

— unresolved issues.

ISO 9001:2000, Quality management systems — Requirements

7 Product realization

7.1 Planning of product realization

The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system.

In planning product realization, the organization shall determine the following, as appropriate:

a) quality objectives and requirements for the product;

b) the need to establish processes, documents, and provide resources specific to the product;

c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;

d) records needed to provide evidence that the realization processes and resulting product meet requirements.

The output of this planning shall be in a form suitable for the organization's method of operations.

NOTE 1 A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan.

NOTE 2 The organization may also apply the requirements given in 7.3 to the development of product realization processes.

7.1.3.3 Product and process validation and changes

Management should ensure that the validation of products demonstrates that they meet the needs and expectations of customers and other interested parties. Validation activities include modelling, simulation and trials, as well as reviews involving customers or other interested parties.

Issues to consider should include

— quality policy and objectives,

— capability or qualification of equipment,

— operating conditions for the product,

— use or application of the product,

— disposal of the product,

— product life cycle,

— environmental impact of the product, and

— impact of the use of natural resources including materials and energy.

Process validation should be carried out at appropriate intervals to ensure timely reaction to changes impacting the process. Particular attention should be given to validation of processes

— for high value and safety critical products,

— where deficiency in product will only be apparent in use,

— which cannot be repeated, and

— where verification of product is not possible.

The organization should implement a process for effective and efficient control of changes to ensure that product or process changes benefit the organization and satisfy the needs and expectations of interested parties. Changes should be identified, recorded, evaluated, reviewed, and controlled in order to understand the effect on other processes and the needs and expectations of customers and other interested parties.

Any changes in the process affecting product characteristics should be recorded and communicated in order to maintain the conformity of the product and provide information for corrective action or performance improvement of the organization. Authority for initiating change should be defined in order to maintain control.

Outputs in the form of products should be validated after any related change, to ensure that the change has had the desired effect.

Use of simulation techniques can also be considered in order to plan for prevention of failures or faults in processes.

Risk assessment should be undertaken to assess the potential for, and the effect of, possible failures or faults in processes. The results should be used to define and implement preventive actions to mitigate identified risks. Examples of tools for risk assessment include

— fault modes and effects analysis,

— fault tree analysis,

— relationship diagrams,

— simulation techniques, and

— reliability prediction.

7.2 Processes related to interested parties

Management should ensure that the organization has defined mutually acceptable processes for communicating effectively and efficiently with its customers and other interested parties. The organization should implement and maintain such processes to ensure adequate understanding of the needs and expectations of its interested parties, and for translation into requirements for the organization. These processes should include identification and review of relevant information and should actively involve customers and other interested parties. Examples of relevant process information include

— requirements of the customer or other interested parties,

— market research, including sector and end-user data,

— contract requirements,

— competitor analysis,

— benchmarking, and

— processes due to statutory or regulatory requirements.

The organization should have a full understanding of the process requirements of the customer, or other interested party, before initiating its action to comply. This understanding and its impact should be mutually acceptable to the participants.

ISO 9001:2000, Quality management systems — Requirements

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

The organization shall determine

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,

b) requirements not stated by the customer but necessary for specified or intended use, where known,

c) statutory and regulatory requirements related to the product, and

d) any additional requirements determined by the organization.

7.2.2 Review of requirements related to the product

The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that

a) product requirements are defined,

b) contract or order requirements differing from those previously expressed are resolved, and

c) the organization has the ability to meet the defined requirements.

Records of the results of the review and actions arising from the review shall be maintained.

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.

Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues, or advertising material.

7.2.3 Customer communication

The organization shall determine and implement effective arrangements for communicating with customers in relation to

a) product information,

b) enquiries, contracts or order handling, including amendments, and

c) customer feedback, including customer complaints.

7.3 Design and development

7.3.1 General guidance

Top management should ensure that the organization has defined, implemented and maintained the necessary design and development processes to respond effectively and efficiently to the needs and expectations of its customers and other interested parties.

When designing and developing products or processes, management should ensure that the organization is not only capable of considering their basic performance and function, but all factors that contribute to meeting the product and process performance expected by customers and other interested parties. For example, the organization should consider life cycle, safety and health, testability, usability, user-friendliness, dependability, durability, ergonomics, the environment, product disposal and identified risks.

Management also has the responsibility to ensure that steps are taken to identify and mitigate potential risk to the users of the products and processes of the organization. Risk assessment should be undertaken to assess the potential for, and the effect of, possible failures or faults in products or processes. The results of the assessment should be used to define and implement preventive actions to mitigate the identified risks. Examples of tools for risk assessment of design and development include

— design fault modes and effects analysis,

— fault tree analysis,

— reliability prediction,

— relationship diagrams,

— ranking techniques, and

— simulation techniques.

ISO 9001:2000, Quality management systems — Requirements

7.3 Design and development

7.3.1 Design and development planning

The organization shall plan and control the design and development of product.

During the design and development planning the organization shall determine

a) the design and development stages,

b) the review, verification and validation that are appropriate to each design and development stage, and

c) the responsibilities and authorities for design and development.

The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output shall be updated, as appropriate, as the design and development progresses.

7.3.2 Design and development input and output

The organization should identify process inputs that affect the design and development of products and facilitate effective and efficient process performance in order to satisfy the needs and expectations of customers, and those of other interested parties. These external needs and expectations, coupled with those internal to the organization, should be suitable for translation into input requirements for the design and development processes.

Examples are as follows:

a) external inputs such as

   — customer or marketplace needs and expectations,

   — needs and expectation of other interested parties,

   — supplier's contributions,

   — user input to achieve robust design and development,

   — changes in relevant statutory and regulatory requirements,

   — international or national standards, and

   — industry codes of practice;

b) internal inputs such as
   - policies and objectives,
   - needs and expectations of people in the organization, including those receiving the output of the process,
   - technological developments,
   - competence requirements for people performing design and development,
   - feedback information from past experience,
   - records and data on existing processes and products, and
   - outputs from other processes;

c) inputs that identify those characteristics of processes or products that are crucial to safe and proper functioning and maintenance, such as
   - operation, installation and application,
   - storage, handling and delivery,
   - physical parameters and the environment, and
   - requirements for disposal of the products.

Product-related inputs based on an appreciation of the needs and expectations of end users, as well as those of the direct customer, can be important. Such inputs should be formulated in a way that permits the product to be verified and validated effectively and efficiently.

The output should include information to enable verification and validation to planned requirements. Examples of the output of design and development include

- data demonstrating the comparison of process inputs to process outputs,
- product specifications, including acceptance criteria,
- process specifications,
- material specifications,
- testing specifications,
- training requirements,
- user and consumer information,
- purchase requirements, and
- reports of qualification tests.

Design and development outputs should be reviewed against inputs to provide objective evidence that outputs have effectively and efficiently met the requirements for the process and product.

ISO 9001:2000, Quality management systems — Requirements

7.3.2 Design and development inputs

Inputs relating to product requirements shall be determined and records maintained. These shall include

a) functional and performance requirements,

b) applicable statutory and regulatory requirements,

c) where applicable, information derived from previous similar designs, and

d) other requirements essential for design and development.

These inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.

7.3.3 Design and development outputs

The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release.

Design and development outputs shall

a) meet the input requirements for design and development,

b) provide appropriate information for purchasing, production and for service provision,

c) contain or reference product acceptance criteria, and

d) specify the characteristics of the product that are essential for its safe and proper use.

7.3.3 Design and development review

Top management should ensure that appropriate people are assigned to manage and conduct systematic reviews to determine that design and development objectives are achieved. These reviews may be conducted at selected points in the design and development process as well as at completion.

Examples of topics for such reviews include

— adequacy of input to perform the design and development tasks,

— progress of the planned design and development process,

— meeting verification and validation goals,

— evaluation of potential hazards or fault modes in product use,

— life-cycle data on performance of the product,

— control of changes and their effect during the design and development process,

— identification and correction of problems,

— opportunities for design and development process improvement, and

— potential impact of the product on the environment.

At suitable stages, the organization should also undertake reviews of design and development outputs, as well as the processes, in order to satisfy the needs and expectations of customers and people within the organization who receive the process output. Consideration should also be given to the needs and expectations of other interested parties.

Examples of verification activities for output of the design and development process include

— comparisons of input requirements with the output of the process,

— comparative methods, such as alternative design and development calculations,

— evaluation against similar products,

— testing, simulations or trials to check compliance with specific input requirements, and

— evaluation against lessons learned from past process experience, such as nonconformities and deficiencies.

Validation of the output of the design and development processes is important for the successful reception and use by customers, suppliers, people in the organization and other interested parties.

Participation by the affected parties permits the actual users to evaluate the output by such means as

— validation of engineering designs prior to construction, installation or application,

— validation of software outputs prior to installation or use, and

— validation of services prior to widespread introduction.

Partial validation of the design and development outputs may be necessary to provide confidence in their future application.

Sufficient data should be generated through verification and validation activities to enable design and development methods and decisions to be reviewed. The review of methods should include

— process and product improvement,

— usability of output,

— adequacy of process and review records,

— failure investigation activities, and

— future design and development process needs.

ISO 9001:2000, Quality management systems — Requirements

7.3.4 Design and development review

At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements

a) to evaluate the ability of the results of design and development to meet requirements, and

b) to identify any problems and propose necessary actions.

Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained.

7.3.5 Design and development verification

Verification shall be performed in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained.

7.3.6 Design and development validation

Design and development validation shall be performed in accordance with planned arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, when known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained.

7.3.7 Control of design and development changes

Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered.

Records of the results of the review of changes and any necessary actions shall be maintained.

7.4 Purchasing

7.4.1 Purchasing process

Top management of the organization should ensure that effective and efficient purchasing processes are defined and implemented for the evaluation and control of purchased products, in order that purchased products satisfy the organization's needs and requirements, as well as those of interested parties.

Use of electronic linkage with suppliers should be considered in order to optimize communication of requirements.

To ensure the effective and efficient performance of the organization, management should ensure that purchasing processes consider the following activities:

— timely, effective and accurate identification of needs and purchased product specifications;

— evaluation of the cost of purchased product, taking account of product performance, price and delivery;

— the organization's need and criteria for verifying purchased products;

— unique supplier processes;

— consideration of contract administration, for both supplier and partner arrangements;

— warranty replacement for nonconforming purchased products;

— logistic requirements;

— product identification and traceability;

— preservation of product;

— documentation, including records;

— control of purchased product which deviates from requirements;

— access to suppliers' premises;

— product delivery, installation or application history;

— supplier development;

— identification and mitigation of risks associated with the purchased product.

Requirements for suppliers' processes and product specifications should be developed with suppliers in order to benefit from available supplier knowledge. The organization could also involve suppliers in the purchasing process in relation to their products in order to improve the effectiveness and efficiency of the organization's purchasing process. This could also assist the organization in its control and availability of inventory.

The organization should define the need for records of purchased product verification, communication and response to nonconformities in order to demonstrate its own conformity to specification.

7.4.2 Supplier control process

The organization should establish effective and efficient processes to identify potential sources for purchased materials, to develop existing suppliers or partners, and to evaluate their ability to supply the required products in order to ensure the effectiveness and efficiency of overall purchasing processes.

Examples of inputs to the supplier control process include

— evaluation of relevant experience,

— performance of suppliers against competitors,

— review of purchased product quality, price, delivery performance and response to problems,

— audits of supplier management systems and evaluation of their potential capability to provide the required products effectively and efficiently and within schedule,

— checking supplier references and available data on customer satisfaction,

— financial assessment to assure the viability of the supplier throughout the intended period of supply and cooperation,

— supplier response to inquiries, quotations and tendering,

— supplier service, installation and support capability and history of performance to requirements,

— supplier awareness of and compliance with relevant statutory and regulatory requirements,

— the supplier's logistic capability including locations and resources, and

— the supplier's standing and role in the community, as well as perception in society.

Management should consider actions needed to maintain the organization's performance and to satisfy interested parties in the event of supplier failure.

ISO 9001:2000, Quality management systems — Requirements

7.4 Purchasing

7.4.1 Purchasing process

The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.

The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained.

7.4.2 Purchasing information

Purchasing information shall describe the product to be purchased, including where appropriate

a) requirements for approval of product, procedures, processes and equipment,

b) requirements for qualification of personnel, and

c) quality management system requirements.

The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

7.4.3 Verification of purchased product

The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.

7.5 Production and service operations

7.5.1 Operation and realization

Top management should go beyond control of the realization processes in order to achieve both compliance with requirements and provide benefits to interested parties. This may be achieved through improving the effectiveness and efficiency of the realization processes and associated support processes, such as

— reducing waste,

— training of people,

— communicating and recording information,

— developing supplier capability,

— improving infrastructure,

— preventing problems,

— processing methods and process yield, and

— methods of monitoring.

ISO 9001:2000, Quality management systems — Requirements

7.5 Production and service provision

7.5.1 Control of production and service provision

The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable

a) the availability of information that describes the characteristics of the product,

b) the availability of work instructions, as necessary,

c) the use of suitable equipment,

d) the availability and use of monitoring and measuring devices,

e) the implementation of monitoring and measurement, and

f) the implementation of release, delivery and post-delivery activities.

7.5.2 Validation of processes for production and service provision

The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.

Validation shall demonstrate the ability of these processes to achieve planned results.

The organization shall establish arrangements for these processes including, as applicable

a) defined criteria for review and approval of the processes,

b) approval of equipment and qualification of personnel,

c) use of specific methods and procedures,

d) requirements for records, and

e) revalidation.

7.5.2 Identification and traceability

The organization can establish a process for identification and traceability that goes beyond the requirements in order to collect data which can be used for improvement.

The need for identification and traceability may arise from

— status of products, including component parts,

— status and capability of processes,

— benchmarking performance data, such as marketing,

— contract requirements, such as product recall capability,

— relevant statutory and regulatory requirements,

— intended use or application,

— hazardous materials, and

— mitigation of identified risks.

ISO 9001:2000, Quality management systems — Requirements

7.5.3 Identification and traceability

Where appropriate, the organization shall identify the product by suitable means throughout product realization.

The organization shall identify the product status with respect to monitoring and measurement requirements.

Where traceability is a requirement, the organization shall control and record the unique identification of the product.

NOTE In some industry sectors, configuration management is a means by which identification and traceability are maintained.

7.5.3 Customer property

The organization should identify responsibilities in relation to property and other assets owned by customers and other interested parties and under the control of the organization, in order to protect the value of the property. Examples of such property are

— ingredients or components supplied for inclusion in a product,

— product supplied for repair, maintenance or upgrading,

— packaging materials supplied directly by the customer,

— customer materials handled by service operations such as storage,

— services supplied on behalf of the customer, such as transport of customer property to a third party, and

— customer intellectual property, including specifications, drawings and proprietary information.

ISO 9001:2000, Quality management systems — Requirements

7.5.4 Customer property

The organization shall exercise care with customer property while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained.

NOTE Customer property can include intellectual property.

7.5.4 Preservation of product

Management should define and implement processes for handling, packaging, storage, preservation and delivery of product that prevent damage, deterioration or misuse during internal processing and final delivery of the product. Management should involve suppliers and partners in defining and implementing effective and efficient processes to protect purchased material.

Management should consider the need for any special requirements arising from the nature of the product. Special requirements can be associated with software, electronic media, hazardous materials, products requiring special people for service, installation or application, and products or materials that are unique or irreplaceable.

Management should identify resources needed to maintain the product throughout its life cycle to prevent damage, deterioration or misuse. The organization should communicate information to the interested parties involved about the resources and methods needed to preserve the intended use of the product throughout its life cycle.

ISO 9001:2000, Quality management systems — Requirements

7.5.5 Preservation of product

The organization shall preserve the conformity of product during internal processing and delivery to the intended destination. This preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

7.6 Control of measuring and monitoring devices

Management should define and implement effective and efficient measuring and monitoring processes, including methods and devices for verification and validation of products and processes to ensure the satisfaction of customers and other interested parties. These processes include surveys, simulations, and other measurement and monitoring activities.

In order to provide confidence in data, the measuring and monitoring processes should include confirmation that the devices are fit for use and are maintained to suitable accuracy and accepted standards, as well as a means of identifying the status of the devices.

The organization should consider means to eliminate potential errors from processes, such as "fool-proofing", for verification of process outputs in order to minimize the need for control of measuring and monitoring devices, and to add value for interested parties.

ISO 9001:2000, Quality management systems — Requirements

7.6 Control of monitoring and measuring devices

The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements.

The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment shall

a) be calibrated or verified at specified intervals or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded;

b) be adjusted or re-adjusted as necessary;

c) be identified to enable calibration status to be determined;

d) be safeguarded from adjustments that would invalidate the measurement result;

e) be protected from damage and deterioration during handling, maintenance and storage.

In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained.

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

NOTE See ISO 10012-1 and ISO 10012-2 for guidance.

8 Measurement, analysis and improvement

8.1 General guidance

8.1.1 Introduction

Measurement data are important for making fact-based decisions. Top management should ensure effective and efficient measurement, collection and validation of data to ensure the organization's performance and the satisfaction of interested parties. This should include review of the validity and purpose of measurements and the intended use of data to ensure added value to the organization.

Examples of measurement of performance of the organization's processes include

— measurement and evaluation of its products,

— capability of processes,

— achievement of project objectives, and

— satisfaction of customer and other interested parties.

The organization should continually monitor its performance improvement actions and record their implementation, as this can provide data for future improvements.

The results of the analysis of data from improvement activities should be one of the inputs to management review in order to provide information for improving the performance of the organization.

8.1.2 Issues to be considered

Measurement, analysis and improvement include the following considerations:

a) measurement data should be converted to information and knowledge to be of benefit to the organization;

b) measurement, analysis and improvement of products and processes should be used to establish appropriate priorities for the organization;

c) measurement methods employed by the organization should be reviewed periodically, and data should be verified on a continual basis for accuracy and completeness;

d) benchmarking of individual processes should be used as a tool for improving the effectiveness and efficiency of processes;

e) measurements of customer satisfaction should be considered as vital for evaluation of the organization's performance;

f) use of measurements, and the generating and communicating of the information obtained, are essential to the organization and should be the basis for performance improvement and the involvement of interested parties; such information should be current, and its purpose should be clearly defined;

g) appropriate tools for the communication of information resulting from the analyses of the measurements should be implemented;

h) the effectiveness and efficiency of communicating with interested parties should be measured to determine whether the information is timely and clearly understood;

i) where process and product performance criteria are met, it may still be beneficial to monitor and analyse performance data in order to understand better the nature of the characteristic under study;

j) the use of appropriate statistical or other techniques can help in the understanding of both process and measurement variation, and can thereby improve process and product performance by controlling variation;

k) self-assessment should be considered on a periodic basis to assess the maturity of the quality management system and the level of the organization's performance, as well as to define opportunities for performance improvement (see annex A).

ISO 9001:2000, Quality management systems — Requirements

8 Measurement, analysis and improvement

8.1 General

The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed

a) to demonstrate conformity of the product,

b) to ensure conformity of the quality management system, and

c) to continually improve the effectiveness of the quality management system.

This shall include determination of applicable methods, including statistical techniques, and the extent of their use.

8.2 Measurement and monitoring

8.2.1 Measurement and monitoring of system performance

8.2.1.1 General

Top management should ensure that effective and efficient methods are used to identify areas for improvement of the quality management system performance. Examples of methods include

— satisfaction surveys for customers and other interested parties,

— internal audits,

— financial measurements, and

— self-assessment.

8.2.1.2 Measurement and monitoring of customer satisfaction

Measurement and monitoring of customer satisfaction is based on review of customer-related information. The collection of such information may be active or passive. Management should recognize that there are many sources of customer-related information, and should establish effective and efficient processes to collect, analyse and use this information for improving the performance of the organization. The organization should identify sources of customer and end-user information, available in written and verbal forms, from internal and external sources. Examples of customer-related information include

— customer and user surveys,

— feedback on aspects of product,

— customer requirements and contract information,

— market needs,

— service delivery data, and

— information relating to competition.

Management should use measurement of customer satisfaction as a vital tool. The organization's process for requesting, measuring and monitoring feedback of customer satisfaction should provide information on a continual basis. This process should consider conformity to requirements, meeting needs and expectations of customers, as well as the price and delivery of product.

The organization should establish and use sources of customer satisfaction information and should cooperate with its customers in order to anticipate future needs. The organization should plan and establish processes to listen effectively and efficiently to the “voice of the customer”. Planning for these processes should define and implement data-collection methods, including information sources, frequency of collection, and data-analysis review. Examples of sources of information on customer satisfaction include

— customer complaints,

— communicating directly with customers,

— questionnaires and surveys,

— subcontracted collection and analysis of data,

— focus groups,

— reports from consumer organizations,

— reports in various media, and

— sector and industry studies.

ISO 9001:2000, Quality management systems — Requirements

8.2 Monitoring and measurement

8.2.1 Customer satisfaction

As one of the measurements of the performance of the quality management system the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.

8.2.1.3 Internal audit

Top management should ensure the establishment of an effective and efficient internal audit process to assess the strengths and weaknesses of the quality management system. The internal audit process acts as a management tool for independent assessment of any designated process or activity. The internal audit process provides an independent tool for use in obtaining objective evidence that the existing requirements have been met, since the internal audit evaluates the effectiveness and efficiency of the organization.

It is important that management ensure improvement actions are taken in response to internal audit results. Planning for internal audits should be flexible in order to permit changes in emphasis based on findings and objective evidence obtained during the audit. Relevant input from the area to be audited, as well as from other interested parties, should be considered in the development of internal audit plans.

Examples of subjects for consideration by internal auditing include

— effective and efficient implementation of processes,

— opportunities for continual improvement,

— capability of processes,

— effective and efficient use of statistical techniques,

— use of information technology,

— analysis of quality cost data,

— effective and efficient use of resources,

— process and product performance results and expectations,

— adequacy and accuracy of performance measurement,

— improvement activities, and

— relationships with interested parties.

Internal audit reporting sometimes includes evidence of excellent performance in order to provide opportunities for recognition by management and motivation of people.

ISO 9001:2000, Quality management systems — Requirements

8.2.2 Internal audit

The organization shall conduct internal audits at planned intervals to determine whether the quality management system

a) conforms to the planned arrangements, to the requirements of this International Standard and to the quality management system requirements established by the organization, and

b) is effectively implemented and maintained.

An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records shall be defined in a documented procedure.

The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results.

NOTE See ISO 10011-1, ISO 10011-2 and ISO 10011-3 for guidance.

8.2.1.4 Financial measures

Management should consider the conversion of data from processes to financial information in order to provide comparable measures across processes and to facilitate improvement of the effectiveness and efficiency of the organization. Examples of financial measures include

— prevention and appraisal costs analysis,

— nonconformity cost analysis,

— internal and external failure cost analysis, and

— life-cycle cost analysis.

8.2.1.5 Self-assessment

Top management should consider establishing and implementing self-assessment. This is a careful evaluation, usually performed by the organization's own management, that results in an opinion or judgement of the effectiveness and efficiency of the organization and the maturity of the quality management system. It can be used by the organization to benchmark its performance against that of external organizations and world-class performance. Self-assessment also aids in evaluating the performance improvement of the organization, whereas the internal audit process of an organization is an independent audit used to obtain objective evidence that existing

policies, procedures or requirements have been met, as it evaluates the effectiveness and efficiency of the quality management system.

The range and depth of self-assessment should be planned in relation to the organization's objectives and priorities. The self-assessment approach described in annex A focuses on determining the degree of the effectiveness and efficiency of the implementation of the organization's quality management system. Some of the advantages of using the self-assessment approach given in annex A are that

— it is simple to understand,

— it is easy to use,

— it has minimal impact on the use of management resources, and

— it provides input for enhancing the performance of the organization's quality management system.

Annex A is only one example of self-assessment. Self-assessment should not be considered as an alternative to internal or external quality auditing. Use of the approach described in annex A can provide management with an overall view of the performance of the organization and the degree of maturity of the quality management system. It can also provide input for identifying areas in the organization requiring performance improvement and in helping to determine priorities.

8.2.2 Measurement and monitoring of processes

The organization should identify measurement methods and should perform measurements to evaluate process performance. The organization should incorporate these measurements into processes and use the measurements in process management.

Measurements should be used for managing daily operations, for evaluation of the processes that may be suitable for small-step or ongoing continual improvements, as well as for breakthrough projects, according to the vision and strategic objectives of the organization.

Measurements of process performance should cover the needs and expectations of interested parties in a balanced manner. Examples include

— capability,

— reaction time,

— cycle time or throughput,

— measurable aspects of dependability,

— yield,

— the effectiveness and efficiency of the organization's people,

— utilization of technologies,

— waste reduction, and

— cost allocation and reduction.

ISO 9001:2000, Quality management systems — Requirements

8.2.3 Monitoring and measurement of processes

The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.

8.2.3 Measurement and monitoring of product

The organization should establish and specify the measurement requirements (including acceptance criteria) for its products. The measurement of product should be planned and performed in order to verify that the requirements of interested parties have been achieved and used to improve the realization processes.

When selecting measurement methods for ensuring that products conform to requirements and when considering customer needs and expectations, the organization should consider the following:

a) the types of product characteristics, which then determine the types of measurement, suitable measurement means, the accuracy required and skills needed;

b) equipment, software and tools required;

c) the location of suitable measurement points in the realization process sequence;

d) characteristics to be measured at each point, and the documentation and acceptance criteria to be used;

e) customer established points for witness or verification of selected characteristics of a product;

f) inspections or testing required to be witnessed or performed by statutory and regulatory authorities;

g) where, when and how the organization intends, or is required by the customer or statutory and regulatory authorities, to engage qualified third parties to perform

   — type testing,

   — in-process inspections or testing,

   — product verification,

   — product validation, and

   — product qualification;

h) qualification of people, materials, products, processes, and the quality management system;

i) final inspection to confirm that verification and validation activities have been completed and accepted;

j) recording the results of product measurements.

The organization should review the methods used for measuring products and the planned records of verification, to consider opportunities for performance improvement. Typical examples of product measurement records that could be considered for performance improvement include

— inspection and test reports,

— material release notices,

— product acceptance forms, and

— certificates of conformity as required.

ISO 9001:2000, Quality management systems — Requirements

8.2.4 Monitoring and measurement of product

The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements.

Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product.

Product release and service delivery shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

8.2.4 Measurement and monitoring the satisfaction of interested parties

The organization should identify the measurement information required to meet the needs of interested parties (other than customers), in relation to the processes of the organization in order to balance the allocation of resources. Such information should include measurements relating to the people in the organization, owners and investors, suppliers and partners, as well as society. Measurement examples are as follows.

a) For people in the organization, the organization should

   — survey the opinions of its people regarding how well the organization satisfies their needs and expectations, and

   — assess individual and collective performances and their contribution to organizational results.

b) For owners and investors, the organization should

   — assess its capacity to attain defined objectives,

   — assess its financial performance,

   — evaluate the impact of external factors on its results, and

   — identify the value contributed by the actions taken.

c) For suppliers and partners, the organization should

   — survey the opinions of suppliers and partners on their satisfaction with the purchasing processes of the organization,

   — monitor and supply feedback on the performance of suppliers and partners and their compliance with the organization's purchasing policy, and

   — assess the quality of product purchased, contributions from suppliers and partners, and mutual benefits derived from the relationship.

d) For society, the organization should

   — define and track suitable data relative to its objectives, in order to achieve satisfactory interaction with society, and

   — periodically assess the effectiveness and efficiency of its actions and the perceptions of its performance by relevant parts of society.

8.3 Control of nonconformity

8.3.1 General

Top management should empower people in the organization with the authority and responsibility to report nonconformities at any stage of a process in order to ensure timely detection and disposition of nonconformities. Authority for response to nonconformities should be defined to maintain achievement of process and product requirements. The organization should effectively and efficiently control nonconforming product identification, segregation and disposition in order to prevent misuse.

Where practical, nonconformities should be recorded, together with their disposition, to assist learning and to provide data for analysis and improvement activities. The organization may also decide that nonconformities to both product realization and support processes should be recorded and controlled.

The organization can also consider recording information on those nonconformities that are corrected in the normal course of work. Such data can provide valuable information for improving the effectiveness and efficiency of processes.

8.3.2 Nonconformity review and disposition

The management of the organization should ensure the establishment of an effective and efficient process to provide for review and disposition of identified nonconformities. Review of nonconformities should be conducted by authorized people to determine if any trends or patterns of occurrence require attention. Negative trends should be considered for improvement, and as input to management review where reduction goals and resource needs are considered.

People carrying out the review should have the competence to evaluate the total effects of the nonconformity and should have the authority and resources to disposition the nonconformity and to define appropriate corrective action. Acceptance of nonconformity disposition may be a contractual requirement of the customer, or a requirement of other interested parties.

ISO 9001:2000, Quality management systems — Requirements

8.3 Control of nonconforming product

The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure.

The organization shall deal with nonconforming product by one or more of the following ways:

a) by taking action to eliminate the detected nonconformity;

b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;

c) by taking action to preclude its original intended use or application.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained.

When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.

When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity.

8.4 Analysis of data

Decisions should be based on analysis of data obtained from measurements and information collected as described in this International Standard. In this context, the organization should analyse data from its various sources to assess performance against plans, objectives and other defined goals, and to identify areas for improvement including possible benefits for interested parties.

Decisions based on facts require effective and efficient actions such as

— valid analysis methods,

— appropriate statistical techniques, and

— making decisions and taking actions based on results of logical analyses, as balanced with experience and intuition.

Analysis of data can help to determine the root cause of existing or potential problems, and therefore guide decisions about the corrective and preventive actions needed for improvement.

For an effective evaluation by management of the total performance of the organization, data and information from all parts of the organization should be integrated and analysed. The organization's overall performance should be

presented in a format that is suitable for different levels of the organization. The results of this analysis can be used by the organization to determine

— trends,

— customer satisfaction,

— satisfaction of other interested parties,

— effectiveness and efficiency of its processes,

— supplier contribution,

— success of its performance improvement objectives,

— economics of quality, financial and market-related performance,

— benchmarking of its performance, and

— competitiveness.

ISO 9001:2000, Quality management systems — Requirements

8.4 Analysis of data

The organization shall determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data shall provide information relating to

a) customer satisfaction,

b) conformity to product requirements,

c) characteristics and trends of processes and products including opportunities for preventive action, and

d) suppliers.

8.5 Improvement

8.5.1 General

Management should continually seek to improve the effectiveness and efficiency of the processes of the organization, rather than wait for a problem to reveal opportunities for improvement. Improvements can range from small-step ongoing continual improvement to strategic breakthrough improvement projects. The organization should have a process in place to identify and manage improvement activities. These improvements may result in change to the product or processes and even to the quality management system or to the organization.

ISO 9001:2000, Quality management systems — Requirements

8.5 Improvement

8.5.1 Continual improvement

The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

8.5.2 Corrective action

Top management should ensure that corrective action is used as a tool for improvement. Corrective action planning should include evaluation of the significance of problems, and should be in terms of the potential impact on such

aspects as operating costs, costs of nonconformity, product performance, dependability and the safety and satisfaction of customers and other interested parties. People from appropriate disciplines should participate in the corrective action process. Also, the effectiveness and efficiency of processes should be emphasized when actions are taken and the actions should be monitored to ensure that desired goals are met. Corrective actions should be considered for inclusion in management review.

In pursuing corrective action, the organization should identify sources of information, and collect information to define the necessary corrective actions. The defined corrective action should be focused on eliminating causes of nonconformities in order to avoid recurrence. Examples of sources of information for corrective action consideration include

— customer complaints,

— nonconformity reports,

— internal audit reports,

— outputs from management review,

— outputs from data analysis,

— outputs from satisfaction measurements,

— relevant quality management system records,

— the organization's people,

— process measurements, and

— results of self-assessment.

There are many ways to determine the causes of nonconformity, including analysis by an individual or the assignment of a corrective-action project team. The organization should balance the investment in the corrective action against the impact of the problem being considered.

In evaluating the need for actions to ensure that nonconformities do not recur, the organization should consider providing appropriate training for people assigned to corrective-action projects.

The organization should incorporate root-cause analysis, as appropriate, into the corrective-action process. Root-cause analysis results should be verified by testing prior to defining and initiating corrective action.

ISO 9001:2000, Quality management systems — Requirements

8.5.2 Corrective action

The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

A documented procedure shall be established to define requirements for

a) reviewing nonconformities (including customer complaints),

b) determining the causes of nonconformities,

c) evaluating the need for action to ensure that nonconformities do not recur,

d) determining and implementing action needed,

e) records of the results of action taken, and

f) reviewing corrective action taken.

8.5.3 Loss prevention

Management should plan to mitigate the effects of loss to the organization in order to maintain the performance of processes and products. Loss prevention in the form of planning should be applied to realization and support processes, activities and products to ensure the satisfaction of interested parties.

To be effective and efficient, planning for loss prevention should be systematic. This should be based on data from appropriate methods, including evaluation of historical data for trends, and criticality relative to the performance of the organization and its products, in order to generate data in quantitative terms. Data can be generated from

— use of risk analysis tools such as fault mode and effects analysis,

— review of customer needs and expectations,

— market analysis,

— management review output,

— outputs from data analysis,

— satisfaction measurements,

— process measurements,

— systems that consolidate sources of information from interested parties,

— relevant quality management system records,

— lessons learned from past experience,

— results of self-assessment, and

— processes that provide early warning of approaching out-of-control operating conditions.

Such data will provide information to develop an effective and efficient plan for loss prevention and prioritization appropriate to each process and product, in order to satisfy the needs and expectations of interested parties.

Results of the evaluation of the effectiveness and efficiency of loss prevention plans should be an output from management review, and should be used as an input for the modification of plans and as input to the improvement processes.

ISO 9001:2000, Quality management systems — Requirements

8.5.3 Preventive action

The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

A documented procedure shall be established to define requirements for

a) determining potential nonconformities and their causes,

b) evaluating the need for action to prevent occurrence of nonconformities,

c) determining and implementing action needed,

d) records of results of action taken, and

e) reviewing preventive action taken.

8.5.4 Continual improvement of the organization

To aid in ensuring the future of the organization and the satisfaction of interested parties, management should create a culture which involves people actively seeking opportunities for improvement of performance in processes, activities and products.

To involve people, top management should create an environment where authority is delegated so that people are empowered and accept responsibility to identify opportunities where the organization can improve its performance. This can be achieved by activities such as

— setting of objectives for people, projects and the organization,

— benchmarking competitor performance and best practice,

— recognition and reward for achievement of improvement, and

— suggestion schemes including timely reaction by management.

To provide a structure for improvement activities, top management should define and implement a process for continual improvement that can be applied to realization and support processes and activities. To ensure the effectiveness and efficiency of the improvement process, consideration should be given to realization and support processes in terms of

— effectiveness (such as outputs meeting requirements),

— efficiency (such as resources per unit in terms of time and money),

— external effects (such as statutory and regulatory change),

— potential weakness (such as lack of capability and consistency),

— the opportunity to employ better methods,

— control of planned and unplanned change, and

— measurement of planned benefits.

Such a process for continual improvement should be used as a tool for improving the organization's internal effectiveness and efficiency, as well as to improve the satisfaction of customers and other interested parties.

Management should support improvements in the form of small-step ongoing activities integral to existing processes as well as breakthrough opportunities, in order to gain maximum benefit for the organization and interested parties.

Examples of inputs to support the improvement process include information derived from

— validation data,

— process yield data

— test data,

— data from self-assessment,

— stated requirements and feedback from interested parties,

— experience of people in the organization,

— financial data,

— product performance data, and

— service delivery data.

Management should ensure that product or process changes are approved, prioritized, planned, provisioned and controlled to satisfy interested party requirements and avoid exceeding the capability of the organization.

A process presenting continual process improvement for implementation by an organization is described in annex B.

Annex A
(informative)

Guidelines for self-assessment

A.1 Introduction

Self-assessment is a carefully considered evaluation resulting in an opinion or judgement of the effectiveness and efficiency of the organization and the maturity of the quality management system. Self-assessment is usually performed by the organization's own management. The intent of self-assessment is to provide fact-based guidance to the organization regarding where to invest resources for its improvement.

It also can be useful in measuring progress against objectives, and to reassess the continuing relevance of those objectives.

Many models currently exist for the self-assessment of organizations to quality management system criteria. The most widely recognized and used models are national and regional quality award models, also referred to as organizational excellence models.

The self-assessment approach described in this annex is intended to provide a simple, easy-to-use approach to determine the relative degree of maturity of an organization's quality management system and to identify the main areas for improvement.

Specific features of the ISO 9004 self-assessment approach are that it can

— be applied to the entire quality management system, or to a part of the quality management system, or to any process,

— be applied to the entire organization or part of the organization,

— be completed quickly with internal resources,

— be completed by a multi-discipline team, or by one person in the organization who is supported by top management,

— form an input to a more comprehensive management system self-assessment process,

— identify and facilitate the prioritization of opportunities for improvement, and

— facilitate maturing of the quality management system towards world-class performance.

The ISO 9004 self-assessment approach is to evaluate the maturity of the quality management system for each major clause in ISO 9004 on a scale ranging from 1 (no formal system) to 5 (best-in-class performance). This annex provides guidance in the form of typical questions that the organization can ask in order to evaluate its performance for each of the main clauses in ISO 9004.

Another advantage to this approach is that results monitored over time can be used to appraise the maturity of an organization.

This approach to self-assessment is neither a substitute for internal audit of the quality management system nor for the use of existing quality award models.

A.2 Performance maturity levels

The performance maturity levels used in this self-assessment approach are shown in Table A.1.

Table A.1 — Performance maturity levels

Maturity level	Performance level	Guidance
1	No formal approach	No systematic approach evident, no results, poor results or unpredictable results.
2	Reactive approach	Problem- or corrective-based systematic approach; minimum data on improvement results available.
3	Stable formal system approach	Systematic process-based approach, early stage of systematic improvements; data available on conformance to objectives and existence of improvement trends.
4	Continual improvement emphasized	Improvement process in use; good results and sustained improvement trends.
5	Best-in-class performance	Strongly integrated improvement process; best-in-class benchmarked results demonstrated.

A.3 Self-assessment questions

The award models as well as other self-assessment models have a wide range of detailed criteria for assessing the performance of management systems. Self-assessment provides an easy approach for evaluating the maturity of an organization based on clauses 4 to 8 of this International Standard. Each organization should develop a set of questions for those clauses of this International Standard that are suitable to its needs. Examples of typical questions for self-assessment are provided below. The subclause numbers are given in parentheses.

Question 1: Managing systems and processes (4.1)

a) How does management apply the process approach to achieve the effective and efficient control of processes, resulting in performance improvement?

Question 2: Documentation (4.2)

a) How are documents and records used to support effective and efficient operation of the processes of the organization?

Question 3: Management responsibility — General guidance (5.1)

a) How does top management demonstrate its leadership, commitment and involvement?

Question 4: Needs and expectations of interested parties (5.2)

a) How does the organization identify customers' needs and expectations on a continual basis?

b) How does the organization identify people's need for recognition, work satisfaction, competence and personal development?

c) How does the organization consider the potential benefits of establishing partnerships with its suppliers?

d) How does the organization identify other interested parties' needs and expectations that can result in setting objectives?

e) How does the organization ensure that statutory and regulatory requirements have been considered?

Question 5: Quality policy (5.3)

a) How does the quality policy ensure that the needs and expectations of customers and other interested parties are understood?

b) How does the quality policy lead to visible and expected improvements?

c) How does the quality policy consider the organization's vision of the future?

Question 6: Planning (5.4)

a) How do the objectives translate the quality policy into measurable goals?

b) How are the objectives deployed to each management level to assure individual contribution to achievement?

c) How does management ensure the availability of resources needed to meet the objectives?

Question 7: Responsibility, authority and communication (5.5)

a) How does top management ensure that responsibilities are established and communicated to people in the organization?

b) How does communicating quality requirements, objectives and accomplishments contribute to improvement of the organization's performance?

Question 8: Management review (5.6)

a) How does top management ensure valid input information is available for the management review?

b) How does the management review activity evaluate information to improve the effectiveness and efficiency of the processes of the organization?

Question 9: Resource management — General guidance (6.1)

a) How does top management plan for resources to be available in a timely manner?

Question 10: People (6.2)

a) How does management promote involvement and support of people for improvement of the effectiveness and efficiency of the organization?

b) How does management ensure that the competence of people in the organization is adequate for current and future needs?

Question 11: Infrastructure (6.3)

a) How does management ensure that the infrastructure is appropriate for the achievement of the objectives of the organization?

b) How does management consider environmental issues associated with the infrastructure?

Question 12: Work environment (6.4)

a) How does management ensure that the work environment promotes motivation, satisfaction, development and performance of people in the organization?

Question 13: Information (6.5)

a) How does management ensure that appropriate information is easily available for fact-based decision making?

Question 14: Suppliers and partnerships (6.6)

a) How does management involve suppliers in the identification of purchasing needs and joint strategy development?

b) How does management promote partnership arrangements with suppliers?

Question 15: Natural resources (6.7)

a) How does the organization ensure the availability of necessary natural resources for its realization processes?

Question 16: Financial resources (6.8)

a) How does management plan, provide, control and monitor the financial resources necessary to maintain an effective and efficient quality management system and to ensure the achievement of the objectives of the organization?

b) How does management ensure awareness of people in the organization about the link between product quality and costs?

Question 17: Product realization — General guidance (7.1)

a) How does top management apply the process approach to ensure the effective and efficient operation of the realization and support processes and the associated process network?

Question 18: Processes related to interested parties (7.2)

a) How has management defined customer-related processes to ensure consideration of customers' needs?

b) How has management defined other interested-party-related processes to ensure consideration of interested parties' needs and expectations?

Question 19: Design and development (7.3)

a) How has top management defined design and development processes to ensure they respond to the needs and expectations of the organization's customers and other interested parties?

b) How are design and development processes managed in practice, including the definition of design and development requirements and the achievement of planned outputs?

c) How are activities such as design review, verification, validation and configuration management considered in the design and development processes?

Question 20: Purchasing (7.4)

a) How has top management defined purchasing processes that ensure purchased products satisfy the organization's needs?

b) How are purchasing processes managed?

c) How does the organization ensure conformity of purchased products from specification through to acceptance?

Question 21: Production and service operations (7.5)

a) How does top management ensure that the input to the realization processes takes account of customers' and other interested parties' needs?

b) How are realization processes managed from inputs to outputs?

c) How are activities such as verification and validation considered in realization processes?

Question 22: Control of measuring and monitoring devices (7.6)

a) How does management control the measuring and monitoring devices to ensure that correct data are being obtained and used?

Question 23: Measurement, analysis and improvement — General guidance (8.1)

a) How does management promote the importance of measurement, analysis and improvement activities to ensure that the organization's performance results in satisfaction of interested parties?

Question 24: Measurement and monitoring (8.2)

a) How does management ensure collection of customer-related data for analysis, in order to obtain information for improvements?

b) How does management ensure the collection of data from other interested parties for analyses and possible improvements?

c) How does the organization use self-assessment of the quality management system for improving the overall effectiveness and efficiency of the organization?

Question 25: Control of nonconformity (8.3)

a) How does the organization control process and product nonconformity?

b) How does the organization analyse nonconformity for lessons learned and process and product improvement?

Question 26: Analysis of data (8.4)

a) How does the organization analyse data to assess its performance and identify areas for improvement?

Question 27: Improvement (8.5)

a) How does management use corrective action for evaluating and eliminating recorded problems affecting its performance?

b) How does management use preventive action for loss prevention?

c) How does the management ensure the use of systematic improvement methods and tools to improve the organization's performance?

A.4 Documentation of self-assessment results

There are many ways to format self-assessment questions to evaluate performance, to indicate maturity ratings and to record possible improvement actions. One approach is shown in Table A.2.

Table A.2 — Example of the recording of self-assessment results

Subclause	Question No.	Actual performance observations	Rating	Improvement action
5.2	4 a)	Our process is better than any other process in the world for this item	5	None required
5.2	4 b)	We have no system for this item	1	Need to structure a process to address this — by WHOM and by WHEN ?

Self-assessment can be used in a flexible way according to the needs of the organization. One approach would be to perform the self-assessment on an individual basis for all or part of the quality management system and then to pursue improvement. Another approach would be to have a cross-functional group of people perform self-assessment on all or part of the quality management system, followed by group review and analysis, then consensus building to determine improvement priorities and action plans. How self-assessment can be effectively and efficiently used in an organization is only limited by the imagination and ingenuity of the individuals in the organization who have an interest in achieving excellence.

A.5 Linking potential benefits of ISO 9004 to self-assessment

There are many different ways to decide what actions should be taken as a result of self-assessment. One approach is to consider the self-assessment output together with the potential key benefits to be gained from a robust quality management system. This approach would enable an organization to identify and initiate improvement projects that would potentially provide the best benefits based on the priority needs of the organization. To facilitate the use of such an approach, examples of potential benefits are given below relating to the questions in A.3 and to particular subclauses of this International Standard. These examples may be used as a starting point to construct a list that is appropriate for the organization. Examples of potential benefits are as follows.

Benefit 1: Managing systems and processes (4.1)

Provides a systematic and visible way to lead and operate an organization that continually improves performance.

Benefit 2: Documentation (4.2)

Provides information and supporting evidence of the effectiveness and efficiency ot the quality management system.

Benefit 3: Management responsibility — General guidance (5.1)

Ensures the consistent and visible involvement of top management.

Benefit 4: Needs and expectations of interested parties (5.2)

Ensures that the quality management system considers, in a balanced way, the needs and expectations of all interested parties, to get an effective and efficient system.

Benefit 5: Quality policy (5.3)

Ensures all interested parties' needs are understood and provides direction to the total organization leading to visible and expected results.

Benefit 6: Planning (5.4)

Translates the quality policy into measurable objectives and plans to provide clear focus on important areas throughout the organization.

Enhances learning from previous experiences.

Benefit 7: Responsibility, authority and communication (5.5)

Provides an organization-wide, consistent and comprehensive approach and clarifies roles and responsibilities and linkages to all interested parties.

Benefit 8: Management review (5.6)

Involves top management in the improvement of the quality management system.

Assesses whether plans have been achieved and indicates appropriate action for improvement.

Benefit 9: Resource management — General guidance (6.1)

Ensures the availability of adequate resources in terms of people, infrastructure, work environment, information, suppliers and partners, natural resources and financial resources so that the objectives of the organization can be achieved.

Benefit 10: People (6.2)

Provides better understanding of roles, responsibilities and goals and enhances involvement at all levels in the organization in order to achieve performance improvement objectives.

Encourages recognition and reward.

Benefits 11, 12, 13 and 15 to: Infrastructure (6.3), Work environment (6.4), Information (6.5) and Natural resources (6.7)

Provide for effective use of resources other than human resources.

Enhance understanding of restrictions and opportunities to ensure that objectives and plans are achievable.

Benefit 14: Suppliers and partnerships (6.6)

Promotes partner relationships with suppliers and other organizations for mutual benefit.

Benefit 16: Financial resources (6.8)

Provides better understanding of the relationship between cost and benefits.

Encourages improvement towards effective and efficient achievement of the organization's objectives.

Benefit 17: Product realization — General guidance (7.1)

Structures the operations of the organization to achieve a desired result.

Benefit 18: Processes related to interested parties (7.2)

Ensures that resources and activities are managed as processes.

Ensures that all interested parties' needs and expectations are understood throughout the organization.

Benefit 19: Design and development (7.3)

Structures the design and development processes to respond effectively and efficiently to the needs and expectations of customers and other interested parties.

Benefit 20: Purchasing (7.4)

Ensures that suppliers are aligned with the organization's quality policy and objectives.

Benefit 21: Production and service operations (7.5)

Ensures sustained customer satisfaction by producing products, delivering services and providing support functions that meet customers' needs and expectations.

Benefit 22: Control of measuring and monitoring devices (7.6)

Ensures the accuracy of data for analysis.

Benefit 23: Measurement, analysis and improvement — General guidance (8.1)

Ensures effective and efficient measurement, collection and validation of data for improvement.

Benefit 24: Measurement and monitoring (8.2)

Provides controlled methods for measurement and monitoring of processes and products.

Benefit 25: Control of nonconformity (8.3)

Provides for effective disposition of nonconformity in products and processes.

Benefit 26: Analysis of data (8.4)

Provides for factual decision making.

Benefit 27: Improvement (8.5)

Increases the effectiveness and efficiency of the organization.

Focuses on prevention and improvement based on trends.

Annex B
(informative)

Process for continual improvement

A strategic objective of an organization should be the continual improvement of processes in order to enhance the organization's performance and benefit its interested parties.

There are two fundamental ways to conduct continual process improvement, as follows:

a) breakthrough projects which either lead to revision and improvement of existing processes or the implementation of new processes; these are usually carried out by cross-functional teams outside routine operations;

b) small-step ongoing improvement activities conducted within existing processes by people.

Breakthrough projects usually involve significant redesign of existing processes and should include

— definition of the objectives and an outline of the improvement project,

— analysis of the existing process (the “as-is” process) and realizing opportunities for change,

— definition and planning of improvement to the process,

— implementation of the improvement,

— verification and validation of the process improvement, and

— evaluation of the improvement achieved, including lessons learned.

Breakthrough projects should be conducted in an effective and efficient way using project management methods. After completion of the change, a new project plan should be the basis for continuing process management.

People in the organization are the best source of ideas for small-step or ongoing process improvement and often participate as work groups. Small-step ongoing process improvement activities should be controlled in order to understand their effect. The people in the organization that are involved should be provided with the authority, technical support and necessary resources for the changes associated with the improvement.

Continual improvement by either of the methods identified should involve the following.

a) Reason for improvement: a process problem should be identified and an area for improvement selected, noting the reason for working on it.

b) Current situation: the effectiveness and efficiency of the existing process should be evaluated. Data to discover what types of problems occur most often should be collected and analysed. A specific problem should be selected and an objective for improvement should be set.

c) Analysis: the root causes of the problem should be identified and verified.

d) Identification of possible solutions: alternative solutions should be explored. The best solution should be selected and implemented; i.e. the one that will eliminate the root causes of the problem and prevent the problem from recurring.

e) Evaluation of effects: it should then be confirmed that the problem and its root causes have been eliminated or their effects decreased, that the solution has worked, and the objective for improvement has been met.

f) Implementation and standardization of the new solution: the old process should be replaced with the improved process, thereby preventing the problem and its root causes from recurring.

g) Evaluation of the effectiveness and efficiency of the process with the improvement action completed: the effectiveness and efficiency of the improvement project should be evaluated and consideration should be given for using its solution elsewhere in the organization.

The process for improvement should be repeated on remaining problems, developing objectives and solutions for further process improvement.

In order to facilitate the involvement and awareness of people in improvement activities, management should consider activities such as

— forming small groups and having leaders elected by the group members,

— allowing people to control and improve their workplace, and

— developing people's knowledge, experience and skills as a part of the overall quality management activities of the organization.

Bibliography

[1] ISO 9000-3:1997, *Quality management and quality assurance standards — Part 3: Guidelines for the application of ISO 9001:1994 to the development, supply, installation and maintenance of computer software*.

[2] ISO 9001:2000, *Quality management systems — Requirements*.

[3] ISO 9004-4:1993, *Quality management and quality system elements — Part 4: Guidelines for quality improvement*.

[4] ISO 10005:1995, *Quality management — Guidelines for quality plans*.

[5] ISO 10006:1997, *Quality management — Guidelines to quality in project management*.

[6] ISO 10007:1995, *Quality management — Guidelines for configuration management*.

[7] ISO 10011-1:1990, *Guidelines for auditing quality systems — Part 1: Auditing*[1)].

[8] ISO 10011-2:1991, *Guidelines for auditing quality systems — Part 2: Qualification criteria for quality systems auditors*[1)].

[9] ISO 10011-3:1991, *Guidelines for auditing quality systems — Part 3: Management of audit programmes*[1)].

[10] ISO 10012-1:1992, *Quality assurance requirements for measuring equipment — Part 1: Metrological confirmation system for measuring equipment*.

[11] ISO 10012-2:1997, *Quality assurance for measuring equipment — Part 2: Guidelines for control of measurement processes*.

[12] ISO 10013:1995, *Guidelines for developing quality manuals*.

[13] ISO/TR 10014:1998, *Guidelines for managing the economics of quality*.

[14] ISO 10015:1999, *Quality management — Guidelines for training*.

[15] ISO/TR 10017:1999, *Guidance on statistical techniques for ISO 9001:1994*.

[16] ISO 10576-1:—[2)], *Statistical methods — Guidelines for the evaluation of conformity with specified requirements — Part 1: General principles*.

[17] ISO/TR 13425:1995, *Guide for the selection of statistical methods in standardization and specification*.

[18] ISO 14001:1996, *Environmental management systems — Specification with guidance for use*.

[19] ISO 14004:1996, *Environmental management systems — General guidelines on principles, systems and supporting techniques*.

[20] ISO/IEC 17025:1999, *General requirements for the competence of testing and calibration laboratories*[3)].

[21] IEC 60300-1:—[4)], *Dependability management — Part 1: Dependability programme management*.

1) To be revised as ISO 19011, *Guidelines on quality and/or environmental management auditing*.

2) To be published.

3) Formerly designated ISO/IEC Guide 25.

4) To be published. (Revision of ISO 9000-4:1993)

[22] *Statistical methods for quality control — Vol.1: Terminology and symbols — Acceptance sampling*. ISO Handbook, 4th edition, 1995.

[23] *Statistical methods for quality control — Vol.2: Measurement methods and results Interpretation of statistical data — Process control*. ISO Handbook, 4th edition, 1995.

[24] *Quality Management Principles Brochure*[5].

[25] *ISO 9000 + ISO 14000 News* (a bimonthly publication which provides comprehensive coverage of international developments relating to ISO's management system standards, including news of their implementation by diverse organizations around the world)[6].

[26] Reference websites: http://www.iso.ch
http://www.bsi.org.uk/iso-tc176-sc2

5) Available from website: http://www.iso.ch

6) Available from ISO Central Secretariat (sales@iso.ch).

Additional resources on the ANSI/ISO/ASQ Q9000:2000 Standards available from ASQ Quality Press:

ISO 9001:2000 Explained, Second Edition
Charles A. Cianfrani, Joseph J. Tsiakals, and John E. (Jack) West
http://qualitypress.asq.org/perl/catalog.cgi?item=H1104

The ISO Lesson Guide 2000: Pocket Guide to Q9001:2000, Second Edition
Dennis Arter and J. P. Russell
http://qualitypress.asq.org/perl/catalog.cgi?item=H1102

ISO 9001:2000 – An Audio Workshop and Master Slide Presentation
John E. (Jack) West and Charles A. Cianfrani
http://qualitypress.asq.org/perl/catalog.cgi?item=H1106

ISO 9001:2000 Quick Reference
Jeanne Ketola and Kathy Roberts
http://qualitypress.asq.org/perl/catalog.cgi?item=H1107

ISO 9000 at the Front Line
William A. Levinson
http://qualitypress.asq.org/perl/catalog.cgi?item=H0987

After the Quality Audit: Closing the Loop on the Audit Process, Second Edition
J. P. Russell and Terry Regel
http://qualitypress.asq.org/perl/catalog.cgi?item=H1070

Internal Quality Auditing
Denis Pronovost
http://qualitypress.asq.org/perl/catalog.cgi?item=H1069

Quality Press has created an ISO 9000:2000 Resource Materials web page. This convenient online resource contains links to all the books, journals, standards, and courses that are available through ASQ (as well as general information and FAQs) on this important revision to the standards. You can visit this page from our Online Bookstore at http://qualitypress.asq.org.

To request a complimentary catalog of ASQ Quality Press publications, call 800-248-1946, or visit our Online Bookstore at http://qualitypress.asq.org.

American Society for Quality

Quality Press
P.O. Box 3005
Milwaukee, Wisconsin 53201-3005
800-248-1946
Fax 414-272-1734
www.asq.org
http://qualitypress.asq.org
http://standardsgroup.asq.org

T2104E